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Care for Women with Newly Diagnosed Breast Cancer

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13. ABSTRACT (Maximum 200 Words) The purpose of the research funded by this grant (DAMD17-94-J-4449) was to determine if advanced practice nurses (APNs) improve quality of life (QOL) and decrease costs of care of women newly diagnosed with breast cancer. In a randomized clinical trial, the control group (n=104) received standard care; the intervention group (n=106) received standard care plus APN interventions. QOL was measured by tests with established reliability and validity at seven intervals over two years. Costs of care were collected through billing records. Uncertainty in illness decreased significantly more from baseline in the intervention group vs. the control group at 1, 3, and 6 months after diagnosis. Intervention and control groups did not differ in mood disturbance or well-being except among unmarried women and women with no history of breast cancer. Intervention and control costs did not differ. In a second descriptive study, similar QOL improvements were demonstrated with a less costly 6-month APN intervention. Qualitative analysis of participants' comments further describes the participants' experiences. In conclusion, APN interventions improved some QOL indicators but did not significantly affect costs. Women newly diagnosed with breast cancer have multiple needs requiring interventions. Further research is critical to maximize both quality and cost outcomes					
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Introduction

Cost-effective methods to manage care for individuals with breast cancer while continuing to achieve quality outcomes is a major healthcare goal. As costs decrease, it is unclear if quality outcomes are being maintained.

An Advanced Practice Nurse (APN) could complement the cancer care team with two major expected outcomes: to improve quality of life (QOL) and decrease costs of care. Evaluation of these quality and cost outcomes of the APN with women newly diagnosed with breast cancer was the purpose of this study.

Hypotheses tested were:

- Women with newly-diagnosed breast cancer who receive continuity of care through advanced nursing care/interventions across the health care settings will achieve a better QOL than patients who do not receive advanced nursing care.
- Women with newly-diagnosed breast cancer who receive advanced nursing follow-up care/interventions will have a lower cost of care than patients who do not receive advanced nursing care.

Methods

Setting

The setting for this study was HealthSystem Minnesota (HSM), an integrated health care system in a suburban community of Minneapolis, Minnesota. This system is comprised of Methodist Hospital (a 426-bed hospital), 21 Park Nicollet Clinics, the Primary Physician Network, The Foundation, and the Institute for Research and Education.

In addition to this system, Fairview Ridges Hospital (a 150-bed hospital located 25 miles from Methodist Hospital) was added as a site in October 1996. The same HSM physicians deliver care at Fairview Ridges for the system's patients in this suburban community and surrounding areas.

Sample

The study sample was female breast cancer patients ≥ 21 years old who were newly diagnosed between February 1995 and May 1997. Patients were identified through pathology departments of both participating hospitals for potential participation in this randomized trial. Physician referral was requested and eligibility criteria were checked. Participant eligibility required women with newly-diagnosed breast cancer to give informed consent, read and write English, and complete questionnaires. Exclusion criteria included a previous diagnosis of cancer, severe psychiatric illness, or comorbidity which severely limited functional ability. In addition, enrollment into the study required women to plan their care within the health system and to give their consent within two weeks of diagnosis. Women who participated from the added site of care (Fairview Ridges Hospital) met the same eligibility criteria as those of the original site (HSM). After the eligibility criteria were met and informed consent was obtained, the women

were randomly assigned by computer-generated blocks of 4 into 1 of 2 groups. Women in the Control group received standard medical care while women in the Intervention group received standard medical care plus advanced nursing care.

Intervention

The intervention was advanced nursing care which consisted of follow-up care and interventions adapted from Brooten's work¹ and the standards of advanced practice in oncology nursing.^{2,3} The advanced nursing care was provided by an APN who is a registered nurse, prepared with a master's degree in nursing, who has in-depth knowledge and skill in the care of a specific patient population. The APN role includes components of patient care: assessment, diagnosis, outcome identification, planning, coordination, health teaching, and consultation. Care was individualized to patient and family needs, based on the expressed needs of the individual, the assessment of the APN, and other health care providers' evaluations. A detailed description of the APN's standard follow-up care for women in this study is in Table 1.

Data Collection

Quality of Life

QOL was measured using three questionnaires: the Mishel Uncertainty in Illness Scale (MUIS), the Profile of Mood States (POMS), and the Functional Assessment of Cancer Therapy (FACT-B). The Mishel Uncertainty in Illness Scale (MUIS) is a 33-item instrument which measures a person's inability to determine the meaning of illness-related events. Four sub-scales measure ambiguity (0-65), complexity (0-35), inconsistency (0-35), and unpredictability (0-25). The sub-scale scores are added for a total MUIS score (0-160). Higher MUIS scores reflect greater uncertainty.⁴

The Profile of Mood States (POMS) consists of 65 adjectives describing feeling and mood used to identify and assess transient, fluctuating affective states. Six sub-scale scores measure tension-anxiety (0-36), depression-dejection (0-60), anger-hostility (0-48), vigor-activity (0-32), fatigue-inertia (0-28), and confusion-bewilderment (0-28). The vigor-activity sub-scale score is subtracted from the summation of the other 5 sub-scale scores for a total mood disturbance score (-32 to +200). Higher POMS scores reflect a greater mood disturbance.⁵

The FACT-B is a 44-item tool measuring self-reported QOL in individuals with breast cancer. Six sub-scale scores measure physical well being (0-28), social/family well-being (0-28), relationships with doctors (0-8), emotional well-being (0-20), functional well-being (0-28), and additional concerns (0-36) related to breast cancer. The FACT-B score (0-148) is the sum of the sub-scale scores. Higher FACT-B scores reflect greater well-being.⁶

After randomization, the initial set of questionnaires and pre-stamped return envelopes were given to the participants to be returned within one week. Subsequent sets of questionnaires and return envelopes were mailed at intervals of 1, 3, 6, 12, 18, and 24 months after enrollment and were to be returned within one week of receiving them. Women who did not return questionnaires received reminder letters mailed after two weeks, telephone calls after four weeks, and additional letters and sets of questionnaires as required.

Costs of Care

Costs of care were collected for each study participant for two years after her date of diagnosis. Although an attempt was made to evaluate costs through a patient diary and the individual's collection of bills, information was incomplete so it was not used for the cost analyses. Costs, in the form of charges and reimbursements, were abstracted from HSM hospital and clinic billing systems. Clinic reimbursements were not obtainable and, therefore, were calculated by multiplying clinic charges by the collection factor. A collection factor was assessed by taking the net revenue received from a participant's insurance product and dividing this revenue by the gross charges assessed to this insurance product. Collection factors were determined on a per charge basis.

The costs of care included fees for provider procedures and services, room utilization, radiological procedures, laboratory tests, hospital/clinic supplies and medications used during the encounter. Some provider fees such as those of the anesthesiologists, emergency room physicians, and radiation oncologists were not accessible so were not included in the cost analyses. The cost data were categorized based on the type of encounter (inpatient hospitalization, outpatient/clinic visit, emergency room visit, urgent care visit, and home care visit) and referenced to the time frames of 0-6 months, 6-12 months, 12-18 months, and 18-24 months. In addition to charges and reimbursements, length of stay information and number of visits were collected.

Upon collecting all costs of care data, the participants were categorized into 4 distinct groups based on the completeness of their cost data. In order to have complete cost data, a participant needed to have all health care services provided by HSM for their entire two-year period of participation in the study. Eligibility criteria attempted to account for this requirement, but could not foresee all potential factors that would make this impossible. Cost categories 1, 2, and 3 included all participants who were HSM patients prior to their cancer diagnosis as determined by their primary care physician and prior billing history. In cost category 1, participants were HSM patients with all cost data available. Cost category 2 participants were HSM patients with all cost data available except for a few procedures or visits at non-HSM facilities. Cost data were provided for these few missing encounters by imputing the mean cost of care for similar category 1 participant encounters. Cost category 3 participants included HSM patients who had complete cost data for only a portion of the two-year period due to participants moving, changing insurance, or transferring care to non-HSM facilities. Cost category 4 included all participants who were not HSM patients prior to their cancer diagnosis as determined by their lack of a HSM primary care physician and lack of billing history or were referred to HSM specialists only. Due to the lack of complete data for cost categories 3 and 4, these participants were not included in the overall costs of care data analyses.

Other cost outcomes were collected through the patient diary which included the patient's recording of events such as their episodes of care, phone calls to health care providers, support services used, time lost from employment, and daycare used. This information from the diaries was not analyzed because the information was incomplete and because reimbursable episodes of care were obtainable from the hospital and clinic billing systems.

Measures of the cost of APN services were based on time logs in which each APN recorded the number of minutes spent with each patient. The logs were completed as the APNs provided care

for the patients during hospitalizations, clinic visits, and home visits. APN time was also recorded for telephone calls, administrative work, and travel mileage to homes. The cost of APN service was calculated by using the formula: APN cost of service per patient = [(average hourly salary + benefits) / 60 minutes per hour x mean APN time per patient in minutes]. A travel cost of \$0.315 per mile was added to the APN cost for home care visits.

Statistical Analysis

Univariate analyses of demographic and QOL data used the t-test for continuous variables and the chi-square test for categorical variables in order to determine whether intervention and Control groups differed significantly. Explanatory variables in all analyses were treated categorically, using categories as indicated in Tables 2, 3, and 4 with the following exceptions: marital status was dichotomized (married / unmarried), and cases with "unknown" values on a variable were excluded from analyses involving that variable.

Analyses of QOL data following baseline used multiple regression methods for repeated measures. These analyses were conducted using the SAS program GENMOD for repeated measures⁷ with specification of the identity matrix as the working correlation matrix. Data from all participants having baseline QOL data and QOL data from at least one of the follow-up periods were included. Regression analyses were also performed on data from each follow-up period individually.

Because charges, reimbursements, and frequency of health care visits were not normally distributed, the nonparametric Wilcoxon-Mann-Whitney test⁸ was used for univariate analyses of these variables. Multivariate regression analyses were conducted on the logarithmic transform of these variables, which showed more normal distributions.

All tests were two-tailed and were considered statistically significant at $P < 0.05$.

Results

Patient Characteristics

Of 558 women with newly-diagnosed breast cancer who were screened at HSM during the study enrollment period, 85 (15%) women were not referred by their physicians and were not approached about the study. After reviewing eligibility criteria of 473 referred patients, 177 (37.4%) patients were determined to be ineligible. Patients were deemed ineligible for the following reasons: a previous diagnosis of cancer ($n = 61$), planning to go outside of HSM for care ($n = 46$), not enrolling in the study within two weeks of being informed of the diagnosis ($n = 39$), comorbidity severely limiting functional ability ($n = 12$), inability to complete questionnaires ($n = 8$), inability to read and write English ($n = 4$), severe psychiatric illness ($n = 4$), and/or inability to give informed consent ($n = 3$). Eighty-five (28.7%) of the 296 eligible patients refused participation. The enrolled sample of 211 (71.3%) women met eligibility criteria and agreed to participate. The sample included 106 patients in the Intervention group, and 105 patients in the Control group. One patient randomized to the Control group was restaged to a non-cancerous condition after enrolling and subsequently withdrawing from the study, decreasing the Control group to 104 patients.

Comparisons between study participants and women who were screened during the study enrollment period but did not participate (nonparticipants) are summarized in Table 2. Participants were significantly younger ($P < 0.0001$) than nonparticipants and were significantly more likely to have invasive disease ($P = 0.003$).

The randomization process produced Intervention and Control groups that were demographically similar. No significant differences were detected between groups in age at diagnosis, years of education, race, marital status, income, or family history of breast cancer (Tables 3 & 4). Payment sources were categorized based on the primary payer source. Three categories included managed care (HMO), fee-for-service (Non-HMO), and Medicare/Medical Assistance. The 2 groups did not differ significantly in payer source (Table 3).

Disease status at the time of breast cancer diagnosis is compared in Table 4. Women in the Intervention group were significantly more likely to have a lower Broder's grade than women in the Control group ($P = 0.04$). Other categories including extent of disease, histology, tumor size, and number of positive nodes were similar.

Breast cancer treatment was similar in the Intervention and Control groups, with the exception that women in the Intervention group were significantly more likely to receive adjuvant hormone therapy ($P = 0.03$) (Table 5). Table 6 shows the number of women included in cost analyses who received each of 10 treatment paths. In addition to these treatments, 3 women, all in the Control group, underwent bone marrow transplant.

The presence of comorbid conditions was determined using oncology registry data abstracted from the medical records for all cases. Based on this information, each case was assigned a value on the Charlson comorbidity index⁹ which is a weighted index that takes into account both the number and the severity of comorbid conditions. The prevalence of comorbid conditions in both Intervention and Control groups was low (83% of cases in each group had Charlson scores of 0), and the distribution of Charlson scores did not differ significantly between Intervention and Control groups ($P = 0.498$).

Quality of Life

The mean number of days after diagnosis for completion of the baseline QOL questionnaires was 12.7 days for the Intervention group and 10.0 days for the Control group. Ninety-five percent of the women completed the baseline questionnaires within 30 days after being informed of their diagnosis and 77% completed them before their definitive surgery. The number of patients completing the QOL questionnaires at baseline and 1, 3, 6, 12, 18, and 24 months following baseline are shown in Table 7. Return rates were significantly higher in the Intervention group than the Control group at all time periods (all P s < 0.05). QOL analyses focused on baseline through 12 months for three reasons: (1) The number responding beyond 12 months was low, particularly in the Control group; (2) The APN intervention itself was reduced beyond 12 months due to decreased patient needs; (3) Comparisons between Intervention and Control groups on QOL scales and subscales showed no significant differences beyond 12 months (t-tests, all P s > 0.05). Overall, scores on the MUIS decreased somewhat at 18 and 24 months, whereas scores on the POMS and FACT-B scales showed little change beyond 12 months.

Figures 1, 2, and 3 show the mean scores on the MUIS, POMS, and FACT-B scales, respectively, at baseline and at 1, 3, 6, and 12 months following baseline.

Baseline

Intervention and Control groups were similar on QOL measures at baseline. MUIS and POMS scores at baseline showed that women in the Intervention group had slightly greater uncertainty and mood disturbance than the Control group, but neither difference was statistically significant ($P = 0.057$ and $P = 0.076$, respectively). Intervention and Control groups did not differ on FACT-B scores at baseline.

Women with greater extent of disease, based on the SEER¹⁰ staging system, had significantly more uncertainty at baseline than those with less extensive disease ($P = 0.043$). Baseline POMS and FACT-B were unaffected by extent of disease. The effect of marital status (married versus unmarried) approached significance for baseline scores on the MUIS ($P = 0.080$) and FACT-B ($P = 0.063$). Married women tended to have less uncertainty and greater well-being at baseline than unmarried women. Baseline POMS was unaffected by marital status.

Age, income, family history of breast cancer, tumor size, and presence of positive nodes did not significantly affect MUIS, POMS, or FACT-B scores at baseline.

Changes from Baseline

Multivariate regression analyses for repeated measures on QOL scores included the following covariates: baseline score on the scale being analyzed, time period (1, 3, 6, 12 months), the variable of primary interest, and any confounding variables. Because the baseline score was included as a covariate, analyses of QOL scores at 1, 3, 6, and 12 months were not influenced by baseline scores. These analyses controlled for any differences at baseline and, thus, essentially assessed differences from baseline.

The effect of time since baseline was significant for all 3 QOL scales (all P s $< .05$), reflecting the patterns evident in Figures 1 – 3. Uncertainty, as assessed by the MUIS, tended to decrease beyond 1 month; mood disturbance, as assessed by the POMS, decreased steadily from baseline; well-being, as assessed by FACT-B, tended to increase beyond 1 month.

MUIS. Several potentially confounding variables were assessed for their individual effects on MUIS scores after adjustment for baseline. Age, income, type of surgery, family history of breast cancer, marital status and presurgical chemotherapy did not affect uncertainty, whereas extent of disease ($P = 0.001$), Broder's grade ($P = 0.044$) chemotherapy ($P = 0.005$), and adjuvant hormone therapy ($P = 0.005$) produced significant effects. Uncertainty was higher for women with more extensive disease or higher grade or for those undergoing chemotherapy, and lower for women who received adjuvant hormone therapy than for those who did not. Subsequent analyses of the effect of group assignment included adjustment for extent of disease and hormone therapy, as well as baseline MUIS scores.

The Intervention group showed significantly lower uncertainty than the Control group after adjustment for baseline MUIS, extent of disease and hormone therapy ($P = 0.043$). There was also a significant interaction of group assignment and time period ($P = 0.005$), indicating that the

effect of the APN intervention was not the same at all time periods. After adjustment for baseline, uncertainty was significantly lower in the Intervention group than the Control group at 1 month ($P = 0.001$), 3 months ($P = 0.026$), and 6 months ($P = 0.011$), but not at 12 months ($P = 0.589$). In addition, uncertainty increased significantly at 1 month following baseline in the Control group ($P = 0.010$) but not in the Intervention group (see Figure 1).

Analyses of MUIS scores also showed a significant interaction of group assignment and marital status ($P = 0.017$), reflecting that the beneficial effect of the APN intervention was greater for unmarried women than for married women. Mean MUIS scores for unmarried women in the Intervention group compared to unmarried women in the Control group are shown in Figure 4.

There was no significant interaction between group assignment and family history of breast cancer, extent of disease, or chemotherapy.

Similar analyses were conducted on each of the 4 subscales of the MUIS in order to elucidate further the effect of the APN intervention. Group assignment, adjusted for extent of disease, hormone therapy, and baseline scores, had significant effects on the complexity, inconsistency, and unpredictability subscales ($P = 0.005$, 0.005 , and 0.038 , respectively). Scores on each of those sub-scales, adjusted for baseline, were lower in the Intervention group than the Control group. The ambiguity subscale showed a significant interaction between group assignment and time period ($P = 0.030$). For women in the Intervention group, a sense of ambiguity regarding the state of their illness either held steady or decreased with time since baseline; for women in the Control group, ambiguity was higher at 1 month than at baseline.

POMS. Effects of income, type of surgery, presurgical chemotherapy, extent of disease, Broder's grade, marital status, and hormone therapy on POMS scores adjusted for baseline were not significant. Effects of chemotherapy ($P = 0.002$) and age ($P = 0.037$) were significant. After adjustment for baseline, women who were 60 years of age or older had less mood disturbance than younger women, and those undergoing chemotherapy had more mood disturbance than those who did not have chemotherapy. The effect of a positive family history of breast cancer was marginally significant ($P = 0.074$). Women with a positive family history tended to have less mood disturbance. Subsequent analyses of POMS scores included adjustment for age and family history, as well as baseline POMS scores.

Intervention and Control groups did not differ significantly on POMS scores ($P = 0.953$). Although group assignment did not interact significantly with extent of disease or chemotherapy, there was a significant interaction between group assignment and marital status ($P = 0.010$), due to the fact that the effect of the intervention was greater for unmarried women than married women. When analyses were restricted to unmarried women (see Figure 5) and adjusted for baseline, the Intervention group showed significantly less mood disturbance on the POMS than the Control group ($P = 0.019$). Follow-up t-tests showed that among unmarried women, mood disturbance decreased from baseline significantly more in the Intervention group than the Control group at 1 month ($P = 0.011$) and 3 months ($P = 0.043$).

None of the 6 subscales of the POMS showed significant differences between Intervention and Control groups when both married and unmarried women were included in the analyses. However, when analysis was restricted to unmarried women, the Intervention group showed

significantly lower scores than the Control group on the following subscales: Tension-Anxiety ($P = 0.027$), Depression-Dejection, ($P = 0.004$), and Anger-Hostility ($P = 0.028$).

Analyses of POMS scores also demonstrated a significant interaction between group assignment and family history of breast cancer ($P = 0.044$). Women with a negative family history for breast cancer benefited more from the intervention than women with a positive family history. When analyses were restricted to women with no family history of breast cancer (see Figure 6), t-tests showed that among these women, mood disturbance decreased from baseline significantly more in the Intervention group than the Control group at 1 month ($P = 0.002$), 3 months ($P = 0.010$), and 6 months ($P = 0.004$). It should be noted, however, that the most striking difference between Intervention and Control groups in this subset was at baseline, where the mean POMS score of the Intervention group was 20 points higher than that of the Control group, for reasons that are not clear. Furthermore, none of the subscales showed a significant difference between Intervention and Control groups when analyses were restricted to women with a negative family history of breast cancer.

FACT-B. Income, type of surgery, family history of breast cancer, Broder's grade, hormone therapy, and marital status did not significantly affect FACT-B scores after adjustment for baseline. The effects of age, chemotherapy, and extent of disease were significant ($P = 0.028$, $P < 0.001$, and $P = 0.030$, respectively). Women in their forties, those undergoing chemotherapy, and those with more extensive disease tended to have the lowest well-being after adjustment for baseline. Subsequent analyses included adjustments for age and extent of disease, as well as baseline FACT-B scores.

Intervention and Control groups did not differ significantly on FACT-B scores ($P = 0.895$) or on any of the sub-scales after adjustment. There was a significant interaction between group assignment and time period ($P = 0.023$), due in part to the larger increase in well-being at 12 months among the Control group (see Figure 3). The interaction of group assignment and marital status was marginally significant ($P = 0.054$). Among unmarried women, those in the Intervention group tended to have greater well-being after adjustment for baseline than those in the Control group (see Figure 7). That advantage was significant only at 1 month following baseline ($P = 0.036$). There was no significant interaction between group assignment and family history of breast cancer, extent of disease, or chemotherapy.

Costs

Cost data in the Intervention group were in cost category 1 for 74 patients, category 2 for 4 patients, category 3 for 4 patients, and category 4 for 24 patients. For the Control group, the corresponding numbers were 67, 7, 5, and 25, respectively. All cost analyses used patients from cost categories 1 and 2 only: a total of 78 women in the Intervention group and 74 patients in the Control group.

Table 8 shows overall charges and reimbursements for Intervention and Control groups during the two-year study period.

There was a wide range of charges (\$9,149 - \$141,734) and reimbursements (\$4,071 - \$114,998) across both groups. Mean charges were \$33,272, and did not differ between Intervention and Control groups. Mean reimbursements were \$9,555 less than charges. There was no significant difference in reimbursements for Intervention and Control groups.

Charges and reimbursements were also categorized by source: inpatient, outpatient or clinic, home care, emergency room or urgent care. The greatest source of charges and reimbursements was outpatient or clinic, followed by inpatient. Home care, emergency room or urgent care use contributed little to cost. Intervention and Control groups did not differ significantly in charges or reimbursements from any of the four sources.

Table 9 shows additional information regarding length of stay and number of health care encounters. The mean length of stay for definitive surgery was 37.8 hours. Intervention and Control groups did not differ significantly on this variable or on mean length of stay for admissions following definitive surgery. Women had an average of 68 health care encounters (inpatient, outpatient/clinic, home care, and emergency room/urgent care) during the two-year period. The mean number of encounters overall did not differ for Intervention and Control groups, nor did the 2 groups differ on number of encounters according to type. Women who had radiation as part of their treatment regimen had 33-37 encounters for this treatment. If women received chemotherapy, they averaged 10 encounters specifically for this treatment. The number of physical therapy and psychiatric visits were also analyzed but did not differ significantly between groups. The percent of women having at least 1 physical therapy visit was 32.0% in the Intervention group and 27.0% in the Control group ($P = 0.498$). The percent having at least 1 psychiatric visit was 17.9% in the Intervention group and 23.0% in the Control group ($P = 0.442$). Among women having at least 1 visit, the mean number of physical therapy visits was 6.0 in the Intervention group and 9.1 in the Control group ($P = 0.107$), and the mean number of psychiatric visits were 8.6 and 6.6, respectively ($P = 0.522$).

Figures 8 to 10 portray how mean charges, reimbursements, and number of visits changed over the course of the two-year period for Intervention and Control groups. All 3 variables were dominated by the first 6-month period; charges, reimbursements and visits declined sharply after 6 months and remained relatively steady thereafter. Intervention and Control groups did not differ significantly in charges, reimbursements, or frequency of visits in any of the 6-month periods (all P s > 0.05).

In order to determine whether there were any subgroups for which costs differed between Intervention and Control groups, results were stratified by several variables and the 2 groups were compared on charges, reimbursements, and number of visits within each stratum. Stratification variables included: age (by decade), marital status, extent of disease (in situ, localized, regional, or distant), participation in cancer trials, and survival status (alive throughout study with no recurrence, alive with recurrence, or died on study). Mean charges, reimbursements, and visits as well as P -values indicating whether Intervention and Control groups differed significantly are shown in Tables 10-14.

Intervention and Control groups differed significantly in only 1 stratum. In stratification by age, results showed that among 60-69 year old women, charges and reimbursements were significantly higher for the Intervention group than the Control group (Table 10). However, among these women, those in the Intervention group tended to have more extensive disease and

were more likely to have reconstructive surgery. When analyses of charges and reimbursements in this age group were adjusted for extent of disease and type of surgery, Intervention and Control groups did not differ significantly from each other ($P = 0.215$ for charges and $P = 0.078$ for reimbursements).

Costs of APN Services

Table 15 shows the mean amount of APN time per patient as well as the mean cost of APN service per patient. Time and cost are also categorized by type of APN service. Overall, APN mean time per patient was 1,377 minutes, for a mean cost of \$629 per patient. Seventy-five percent of APN time (and cost) occurred during either clinic visits or telephone visits. APN mean time per patient was greatest (746 minutes per patient) during the first 6 months, dropped substantially in the second and third 6-month periods (240 and 170 minutes respectively), and was least (159 minutes per patient) during the last 6 months of their participation in the study.

Discussion

APN interventions have been shown to improve QOL and decrease costs in many patient populations. In some cancer patient groups, APN interventions have been shown to improve QOL, but no cost studies have been done. This study was designed to determine whether APN interventions improve QOL and reduce costs.

Our first hypotheses was partially confirmed: interventions performed by APNs significantly improved several aspects of QOL for women newly diagnosed with breast cancer. During each of 3 measurement periods, uncertainty decreased significantly more in the Intervention than the Control group. Uncertainty actually increased in the Control group at 1 month from baseline. The increased level of uncertainty at this vulnerable time after breast cancer diagnosis reflects patients' needs for assistance to sort through and process information.

The APN interventions significantly improved women's perceptions of the complexity, inconsistency, and unpredictability of information about their illness and outcome. With the continuity of care and information provided by the APNs, the Intervention patients found their treatment and system of care easier to understand, were less likely to receive conflicting or changing information, and considered their illness and treatment more predictable than Control patients. The coordination of care may have improved the adjustment to the diagnosis and treatment as was suggested in Christman's study of uncertainty during radiotherapy.¹¹

Changes from baseline in mood and well-being did not differ significantly between the Intervention and Control groups. Uncertainty about illnesses has predicted greater disturbance in mood and well-being in other research as well as in the data from this study.¹² At baseline, the MUIS was a significant predictor of every sub-scale of POMS and FACT-B ($P < 0.01$ for each). One might have expected a significant improvement in mood and well-being with the improvement in uncertainty of women in the Intervention group during the first 6 months after diagnosis. Low power due to higher variance in the POMS scale may have contributed to the lack of a significant effect in mood states. However, power does not seem to be the reason for lack of significant difference in well-being. The FACT-B scale was originally developed with

patients having advanced (Stage III or IV) cancer. It may not have been sensitive to group differences with early stage cancer (Stage 0, I or II) which included 58% of the Intervention group and 70% of the Control group. The clinical value of the interventions seemed apparent and was validated in the qualitative analysis of verbalized and written comments about the positive aspects of the nurse intervention on the Intervention group's lives and sense of well-being.

Some sub-groups of patients benefited more than others from APN interventions. The encounters improved mood and well-being, and decreased uncertainty for unmarried women. Unmarried women in the Intervention group also showed greater improvement in the subscales of anxiety, depression, and anger than unmarried women in the Control group. Social support is recognized as a key factor in the acute adjustment to the diagnosis and treatment of cancer.^{13,14} Perhaps unmarried women did not have the same type of support system as married women and benefited more from the APN support and other interventions. In mood states, women without a family history of breast cancer benefited more from the APN interventions than women with a family history indicating that the APN interventions were more important for women without prior family experience with breast cancer.

As in other studies,^{15,16} QOL indicators were most compromised in the first 6 months after diagnosis. The decreased need for the interventions for longer time intervals may account for the absence of group differences beyond this initial time period. Interventions that are shorter, more structured, and more focused to the first 6 months after diagnosis may be appropriate.

Our second hypothesis was not confirmed: costs of care were not decreased by the intervention. There are several possible reasons for this lack of difference. The highest source of charges came from clinic/outpatient visits and many of these could not be altered by the APN interventions. For example, over half of the Intervention (64%) and Control groups (55%) were treated with 33-37 radiation treatments, and over 40% of both groups received chemotherapy. The hypothetical savings provided by the APN interventions may not have been large enough to offset the high treatment-related costs during these clinic/outpatient visits.

Secondly, a mean number of 41 patient-APN phone interactions also complemented the care of women in the Intervention group. These phone interactions may have decreased uncertainty and physician workload as was recognized by many of our system's physicians and has been demonstrated in telephone triage studies.^{17,18} However the number of outpatient visits was not decreased in the Intervention group. This finding supports the need to study whether APN telephone encounters with breast cancer patients can be constructed to decrease physician and other providers' workloads, thus reducing costs.

Readmissions, Emergency and Urgent Care visits were minimal for both the Intervention and Control groups and did not substantially contribute to costs of care. The average hospital length of stay (LOS) was similar between groups for the initial breast surgery with 33% of the women staying less than 24 hours. The LOS was not decreased by the APN intervention for several possible reasons: 1) physician impact on discharge time; 2) LOS already minimized for this group of patients; 3) pending legislation regulating LOS for patients requiring breast cancer surgery.¹⁹ The Oncology Nursing Society's position statement for women requiring breast cancer surgery further supported LOS based on individual physical and psychological ability to

manage at home.²⁰ Other studies had significant cost savings with the APN interventions because of the reduction in hospital LOS, readmissions, ER, or Urgent Care visits.²¹⁻²⁵

Limitations of this randomized trial must be considered. Our study sample was primarily Caucasian, middle-income women with a high level of education. Standardization of care and our competitive managed care environment provide the impetus to not only decrease costs but to continually implement changes which will improve quality of care. Process improvements were implemented during the study period which may have improved overall care and made statistically significant results more difficult to ascertain. Analyses of the actions of a single provider group like the APNs may be difficult to isolate since other providers in the course of treatment also influence patient outcomes. Even though QOL, psychological status, behavior, knowledge, and utilization are considered to be nurse sensitive outcomes, they may elude standard psychometric evaluation.²⁶⁻²⁹ Missing data on QOL and cost measures may have contributed to a lack of power in the analyses. In addition, multiple statistical comparisons increase the possibility that some could have been significant by chance.

Through the intervention in this study, health care providers seemed to realize both the importance of the intervention and the need to further structure the intervention. Strong structural elements of the intervention increase the probability of positive change in outcomes.³⁰ The intervention was loosely structured due to the variable needs of the women diagnosed with breast cancer and the individualized care already provided by the health care team. As the APNs gained experience in working with the women diagnosed with breast cancer and the rest of the health care team, the intervention became better defined. This more structured intervention was the impetus for development of a second study supported by this grant which is discussed in the next pages of this report.

Six-Month Intervention for Newly-Diagnosed Breast Cancer Patients

Introduction

Based on information gathered from the randomized study, 3 time periods were identified as times of greatest patient needs. These time periods are: 1) when patients are informed of their diagnosis, 2) during the perioperative period, and 3) during radiation and chemotherapy. These time periods concur with Holland's crisis points along the illness trajectory.³¹ Based on this information, this second study was conducted to further structure the APN intervention and analyze outcomes of women newly diagnosed with breast cancer.

Objectives

Three specific objectives of the study were to: 1) describe the QOL experienced by patients with newly-diagnosed breast cancer who are included in the revised APN program of care during the first 6 months following diagnosis, 2) document the time and cost of service for the revised APN program of care, 3) expand the eligibility criteria from the original study to further generalize the results to other women with breast cancer.

Methods – Study 2

Patients were eligible for the second study if they were newly diagnosed with breast cancer, received initial treatment at HSM, understood English, and were able to give consent. They were not excluded for a prior cancer diagnosis, because of psychiatric illness or other comorbidities as in the original study.

Intervention

In the second study, the APN met in consultation with patients at the time of diagnosis. After informed consent, written and verbal information were given about breast cancer, what to expect in consultation with physicians, decision-making support, answering questions, and being present during consultations for support. After the initial contact, the APN followed with a telephone call to reinforce the information given and answer participants' questions.

The second phase of care began when definitive surgery was scheduled. The intervention included an individualized education session discussing expectations of surgery, side effects such as pain and nausea management, activity and plan of care tailored to individual patient need and surgeon preference. Anticipated hospital length of stay was also discussed with the patient. If appropriate, a home care referral was initiated to continue care after surgery. Direct nursing care, coordinated and administered by the APN, was provided to patients including assessment, development of a comprehensive care plan, and application of clinical treatments. Patients were again instructed to call the APN as needed with any questions or concerns. A post-operative phone call or home visit was made by the APN to assess the patient's status, reinforce discharge information and provide additional care as needed by the patient.

The third phase of care began prior to initiation of radiation therapy or adjuvant chemotherapy and continued during active treatment. Interventions included assessment of physical and psychosocial needs, education about treatments, symptom management, and care coordination.

During this period, additional visits or telephone calls were provided as needed by the patients. If the patient did not receive adjuvant treatment, a follow-up phone call was made to identify and assist with other follow-up needs.

After treatment was completed, interventions included assessment of ongoing needs such as management of lymphedema and hot flashes, education about long term issues, and coordination of follow-up mammograms and visits.

Similar to the randomized trial, QOL was measured with the MUIS, POMS, and FACT-B. Measurements were obtained at baseline (within two weeks of diagnosis), and at 3 and 6 months following baseline. Charge and reimbursement data were not collected in the second study. APN time was measured as in the first study: $\text{APN cost of service/patient} = [(\text{average hourly salary} + \text{benefits}) / 60 \text{ minutes per hour} \times \text{mean APN time per patient in minutes}]$. The cost of travel to home care visits was calculated using \$.315/mile. A comparison was made between the amount of time and cost of service for the intervention in the first 6 months of the two studies.

QOL scores were compared between the two studies at baseline and at 3 and 6 months following baseline using t-tests. A repeated measures multivariate regression analyses was done adjusting for baseline measures, extent of disease, and tumor size to determine if QOL was compromised by a less time-intensive intervention in the second study.

Results – Study 2

Patient Characteristics

A convenience sample of 47 women newly diagnosed with breast cancer was enrolled in the second study. Demographic and tumor characteristics are listed in Table 16. Patients were similar in both studies in mean age, race, marital status, insurance type, histology and grade. In comparison to women enrolled in the randomized trial, Study 2 patients had a smaller mean tumor size (1.6 vs. 2.0 cm) and less regional/distant disease (23% vs. 36%). Patients had a similar number and severity of comorbidities as measured by the Charlson comorbidity index ($P = 0.836$).

Quality of Life

QOL questionnaires were completed and returned by the majority of participants at all time periods: baseline (100%), 3 months (96%), and 6 months (91%). Figures 11 to 13 show the mean MUIS, POMS and FACT-B scores at baseline and at 3 and 6 months following baseline for the intervention patients in the randomized clinical trial and Study 2. There were no significant differences between the two studies' QOL scores using multivariate repeated measures regression analysis when adjusting for baseline, extent of disease, and tumor size. However, individual t-tests on differences from baseline showed that patients in Study 2 had greater reduction of uncertainty from baseline to 3 months ($P = 0.038$).

Cost

The APN intervention time during the initial 6 months was significantly less in Study 2, decreasing from 747 to 457 minutes per patient from the randomized trial. This accounted for a \$135 (39%) decrease in costs in Study 2 compared to the first six months of the randomized trial (Table 17).

Discussion – Study 2

Even though the mean cost of service per patient in Study 2 was less than for the intervention patients in the randomized trial, similar improvements in patients' QOL were noted over the first 6 months. A likely reason for the cost saving was that the APNs became more efficient in their services as they developed expertise in their role. Physicians and other providers also became accustomed to the APN role and knew when and how to make appropriate referrals. The APNs also conducted a greater percentage of their services via phone consultations rather than in home care, clinic or hospital visits. This is shown in the decrease in the percentage of time spent on clinic or hospital visits, and time and mileage spent on home care visits in Study 2.

The intervention period was shortened from 2 years to 6 months in Study 2. The first 6-month focus was because patients experience the greatest uncertainty, disruption in moods and overall well-being at diagnosis, during the perioperative period, and during active treatment. This is the time period when patients are vulnerable to the physical and psychological consequences of a new breast cancer diagnosis and the rigors of multiple treatments, and thus the APN interventions may be of the most benefit.

A limitation of the second study is that there was no direct comparative group. Although we did not exclude women in the second study with a previous diagnosis of cancer, severe psychiatric illnesses or other co-morbidities as in the first study, the patients were very similar, except for a smaller mean tumor size and lesser extent of disease in the second study. These factors were controlled for in the analysis of QOL scores.

By expanding the eligibility criteria, we attempted to obtain more generalizable results than in the randomized study. We had a lower refusal rate (11.5% in this study versus 28.7% in the previous study), and a slightly higher return rate for the questionnaires (96% versus 93%). In Study 2, the APNs did the informed consent with the patients. This interaction and the patient knowledge through informed consent that they would receive the intervention as a result of participating in the study could have improved participation in the second study.

Qualitative Data Analysis

Purpose

Participants in the randomized clinical trial submitted unanticipated data which described their QOL outcomes and experiences with breast cancer. This rich source of data prompted consultation with a qualitative analysis data expert from the University of Minnesota, Dr. Cynthia Peden-McAlpine. The purpose of the consultation and subsequently the qualitative analysis was to further describe QOL outcomes by analyzing the narrative data submitted by the participants in the randomized clinical trial.

Sample

Of 210 women, 143 (68%) who participated in the randomized trial commented regarding their QOL experiences. Of these participants, 71 were in the experimental group, 57 in the Control group, and 15 had withdrawn from the study.

Data Collection

Diaries were collected every 6 months during the 2 year study in which the participants answered questions for the study but also wrote about their experiences. Unsolicited letters, phone calls, and end-of-study questionnaire comments also provided information and were included in the content analysis.

Data Analysis

Weber's content analysis methodology³² was used to analyze the data. Analysis involved multiple readings of the text, classifying text into content categories, describing the categories and illustrating with text, testing intercoder reliability with the four-member team, and making revisions in the coding until high intercoder agreement was obtained. Reliability of this methodology is assessed by stability, reproducibility, and accuracy.^{32,33} Validity is established by assessing correspondence between the classification scheme and the theoretical framework of the study as well as between the classification scheme and the inferences made about the categories.^{32,33} Content analysis yields measures where the sender and the receiver are unaware of the text being analyzed so there is little danger of confounding the data as it is written.

Results

Findings are described in two categories: the experience of QOL with the diagnosis of breast cancer and the impact of the APNs on QOL. These categories are further described in subcategories based on the themes of the comments. Although the subcategories are separated into physical and emotional, both are reflective of each other and the entire experience of the women diagnosed with breast cancer. Many comments were coded in each category but a selected few most illustrative of the descriptors, are highlighted in the subcategories. The experiences of women in both groups are reported with distinct differences in the nature of the comments between the 2 groups, including more physical and emotional distress in women who did not have the APN intervention. Results are as follows:

I. QOL of women with a diagnosis of breast cancer

A. Recovering the physical self – issues that surfaced during the diagnostic and treatment phases

1. Decision making about treatment

“Someone should meet with the woman before surgery and give different reading materials on whether to have implants or not – both sides should be discussed.”

2. Physical symptoms: insomnia, fatigue, pain, nausea, hot flashes

“The hot flashes were infernos spaced close together spoiling sleep and embarrassing in the daytime... my glasses steamed over.”

“I will need three to four more inflations (of the breast implant). Hopefully now gravity will start pulling it down and it won’t be so high up and hurt so much.” (In a latter diary entry, she commented)... “I still hurt so much everyday no matter what I do.”

3. Functional difficulties caused by cancer treatment

“It was hard to know what to wear (as a bra) during radiation. I wish there was more help in understanding the problems of swelling and discomfort from the lymph nodes and better bras to wear.”

B. Psychosocial problems – issues that surface throughout the trajectory of the illness

1. Fear and uncertainty with diagnosis

“The wait between the mammogram results and the actual diagnosis (a week) was agonizing.”

2. Fear of recurrence

“It’s always a little unnerving – when it’s time for the blood tests. I pray a lot that the cancer is gone and won’t return. I hope I’m not kidding myself!”

3. Depression

“I have been very sad and afraid, my dad is dying and I feel sure my cancer has spread.”

“Handling a classroom of 6th graders and battling the depression I have been feeling since Feb 1st, were just too much – My primary doctor suggested taking a second medical leave when she saw me in April, while I try medication and get psychotherapy. This depression is really a challenge which I never dreamed I would have to deal with...”

3. Changes in body image, sexuality

“Some of the months long after my surgery were more difficult than the time immediately after my surgery. I think we deal with some of the emotional issues one layer at a time. I would step out of the shower six months after the mastectomy, catch my image in the mirror, and want to cry.”

“My legs have been nervous all day. I’m going crazy...I looked in the mirror today when I took off my wig. I look like an orangutan.”

“Encourage doctors to give patients a way to discuss intercourse during treatment. A questionnaire might be helpful to open up communication. This would improve quality of life.”

C. Reconstituting emotional integrity

1. Developing a “fighting spirit”

“OK – they say I have a malignancy in my right breast. Today we drove in a snowstorm to select a date for lumpectomy and future radiation therapy. I am comfortable with the caring staff at XXX... They are professionals. I have lots of

literature, books, etc...and have all I need to learn about this cancer. I am ready for a fight and intend to lick this 100%."

2. Utilizing social support

"This has been a difficult time for myself and my family but I seem to do okay with the support of my husband and children. One of my sons moved home in August because of personal reasons and it is very helpful to have him here. He is very supportive and always has something nice to say to his mom."

"My family was a very necessary factor in my recovery. I cannot imagine going through this if I had no one."

3. Use of spiritual resources

"I received unlimited comfort from my faith in God. I was never disappointed."

"...I don't know how I would of made it through this year if it hadn't been for my strong faith in God!!! I pity people that don't believe."

D. Moving beyond the illness experience

1. Healing and reintegration of body/mind/spirit into a whole

"Cancer is a wake up call for me. I believe that life is too short to do what you don't want to or to be unhappy. It is a message for me to take care of myself and model self-care to others."

2. Personal growth – new appreciation for everyday life

"I continue on my journey which will soon be 10 months since diagnosis. I truly believe I have grown from the perspective of finding joy not from the large scale but from a small scale. Joy in the birds, blue sky, a hug, acts of kindness, sunshine, good health..."

3. Personal growth – refocusing from the negative consequences of their illness to the positive aspects of life

"I enjoy my life, live by myself comfortably, love my full-time job...I have a positive outlook, love to travel, and treasure my family and friends."

4. Interest in civic responsibility

"I have been volunteering for the Race for the Cure – I really liked working with the RFTC volunteers and the race itself was overwhelming."

II. Role of the advanced practice nurse

A. Supportive counselor

1. Educator and facilitator of understanding

"...they are there for the medical questions and all without having to disturb the doctor's office. It helps to lower my anxiety..."

2. Trusted advocate

"I feel strongly about the positive impact my nurse coordinator had in helping me deal with all aspects of treatment... it made a huge difference to have an advocate with a personal touch."

"...provide a nurse coordinator for every patient. The sense of security this provides for the frightened patient is amazing. This was so helpful to know you could call a nurse in the evening and get some practical knowledgeable help..."

"My nurse...was one of the main reasons that I got through the course of my treatment so well...she was both a friend and a person that I could rely on."

3. Provider of support through human presence

"My arm swelled up one night and my husband was out of town, she (the APN) spent the entire night at the Emergency Room with me...for someone to take time out of her private life to spend with me, was truly an act of kindness..."

"...due to anxiety of each chemo it's a help she is there and I also know she is only a telephone call away."

4. Compassionate caregiver

"I am sure I wouldn't be feeling as well as I do mentally if it were not for Mary...she was there when I needed her. She answered every question. She reassured me. She is a wonderful and caring person..."

B. Coordinator of care

1. Management of symptoms

"...suffering from abdominal pain...after an hour I called Mary for advice (Friday evening). I took her advice and within the next hour – the pain was gone. She saved us a call to the emergency room."

"...the nausea returned five days after, I asked Lynn and she called and got a new nausea med..."

2. Continuity of care

"I was very lucky to be a candidate in this study. I'm absolutely sure without the help of the nurse coordinators, I would not have had the length of time the doctors thought I would...because they were there it left me with time to use for quality time for my faith, family, and friends. When there were questions from someone that I could not answer, they could and therefore saving the energy level for people instead of phone calls and paperwork."

Discussion

The description of the experiences of women with breast cancer as they eloquently articulated, merit additional focus and study. Decision making, symptom management, functional abilities, fear and uncertainty, depression, body image and sexuality were all major factors which affected QOL of many of the women in this study. Their QOL was compromised, yet the women in the Intervention group recognized improved QOL as they were dealing with their diagnosis because of the APN interventions.

Implications

Participants expressed the importance of assistance with decision making about treatment options and reconstructive surgery. They highlighted the value of anticipatory guidance to deal with the physical and psychosocial changes experienced with diagnosis and treatment. Other areas of focus included screening for depression, developing effective strategies to deal with anxiety and uncertainty issues surrounding risk of recurrence, and developing methods to increase self-esteem for women experiencing extensive body image changes. Because some symptoms, such as hot flashes, fatigue, and lymphedema, may be long term, is it important to find effective ways to manage these symptoms. Future research is needed on interventions that enhance recovery during breast cancer and facilitate holistic healing and personal growth.

Key Research Accomplishments

The randomized clinical trial, study 2, and the qualitative analysis have provided the following key research accomplishments:

- The randomized clinical trial demonstrated improvement in quality of life (QOL) of women diagnosed with breast cancer as shown by decreased uncertainty with the strongest effects on complexity, inconsistency, and unpredictability of their health care.
- APN interventions were more beneficial in affecting uncertainty, mood and/or well-being for unmarried women and for women with no family history of breast cancer.
- Costs as measured by charges and reimbursement were not decreased by the APN interventions as described in the randomized trial.
- A more structured APN intervention limited to the first 6 months after diagnosis of breast cancer is less costly yet provided similar QOL outcomes.
- Qualitative analyses of women experiencing the diagnosis of breast cancer provides further direction to systematic study and improving QOL of women diagnosed with breast cancer.

Reportable Outcomes

1995

Schroeder L, Sladek (Geditz) M. Evaluation of the breast cancer nurse coordinator: Utilizing presence in advanced practice. Poster presentation at the University of Chicago Hospital's 10th Annual Nursing Research Symposium, Chicago, IL, November 17, 1995.

1996

Sladek (Geditz) M, Schroeder L. Developing a critical pathway: Early discharge following breast cancer surgery utilizing the breast cancer nurse coordinator. Poster presentation at the 21st Annual Congress of the Oncology Nursing Society, Philadelphia, PA, May 2-5, 1996.

Sladek M, Schroeder L. Early discharge following breast cancer surgery: Utilizing home care nurses in the surgical setting. Podium presentation at the University of Chicago Hospitals 11th Annual Nursing Research Symposium, Chicago, IL, November 15, 1996.

1997

Sladek M, Schroeder L. Cost analysis of breast cancer surgery: Outpatient surgery versus hospital admission. Podium presentation at the Fourth National Conference on Cancer Nursing Research, Panama City, FL, January 23-25, 1997.

Sladek M, Schroeder L, Ritz L. Cost comparison of breast cancer surgery: Outpatient surgery versus hospital admission. Podium presentation at the 22nd Annual Congress of the Oncology Nursing Society, New Orleans, LA, May 1-4, 1997.

Ritz L, Swenson K, Sperduto P. Evaluation of nursing care for women with newly-diagnosed breast cancer. Poster presentation at the Department of Defense Era of Hope Breast Cancer Conference, Washington, DC, November 14, 1997.

1998

Sladek M, Schroeder L, Ritz L. Cost comparison of breast cancer surgery: Outpatient surgery versus hospital admission. Podium presentation at the Seventh Annual Nursing Research Conference, Mayo Clinic, Rochester, MN, February 16, 1998.

Sladek M, Schroeder L, Swenson K, Ritz L. (Karen Swenson presenter). Satisfaction with the one day breast cancer surgery home care nurse program. Podium presentation at the 23rd Annual Congress of the Oncology Nursing Society, San Francisco, CA, May 7-10, 1998.

Ritz LJ, Farrell JB, Swenson K. Physician attitudes towards the advanced practice nurse's role in care of women with breast cancer. Podium presentation at the 23rd Annual Congress of the Oncology Nursing Society, San Francisco, CA, May 7-10, 1998.

New programs aim to improve home care services. *Oncology News International*, 7(11), 1998. Review of Podium presentation at the 23rd Annual Congress of the Oncology Nursing Society, San Francisco, CA: Sladek M, Schroeder L, Ritz L, and Swenson K. Satisfaction with the one day breast cancer surgery home care nurse program.

1999

Lally RM, Sladek M, Swenson KK. Discharge readiness and satisfaction among breast cancer patients receiving presurgical education from advanced practice nurses. Poster presentation at the 5th National Conference on Cancer Nursing Research, Newport Beach, CA, February 11-13, 1999.

Ritz LJ, Nissen MJ, Swenson KK, Farrell JB, Sladek M, Lally R, Sperduto PW. Effects of advanced nursing care on costs and quality of life of women newly diagnosed with breast cancer. Poster presentation at the 4th Annual Multidisciplinary Symposium on Breast Disease, Amelia Island, FL, February 11-14, 1999.

Ritz L. Effects of advanced nursing care on quality of life of women newly diagnosed with breast cancer. Podium presentation at the Institute for Research and Education monthly FIRE meeting, HealthSystem Minnesota, Minneapolis, MN, March 22, 1999.

Lally RM, Sladek M, Swenson KK. Discharge readiness and satisfaction among breast cancer patients receiving presurgical education from advanced practice nurses. Podium presentation at the 24th Annual Congress of the Oncology Nursing Society, Atlanta, GA, April 28 – May 1, 1999.

Sladek M, Lally R, Ritz L. Patient preparedness: Responding to the needs of women undergoing breast cancer surgery. Poster presentation at the 24th Annual Congress of the Oncology Nursing Society, Atlanta, GA, April 28 – May 1, 1999.

Lally R. Discharge readiness and satisfaction among breast cancer patients receiving presurgical education from advanced practice nurses. Podium presentation at the University of Minnesota School of Nursing Spring Research Day: Achieving Excellence in Nursing Through Research, Minneapolis, MN, May 4, 1999.

Sladek ML, Swenson KK, Ritz LJ, Schroeder LM. A critical pathway for patients undergoing one-day breast cancer surgery. Published in the *Clinical Journal of Oncology Nursing*, July 1999, 3(3):99-106.

Lally RM, Sladek ML, Swenson KK, Ritz LJ. Innovative services of advanced practice nurses meet the challenges of breast cancer care. Poster presentation at the Seeking Excellence in Breast Cancer Care: Best Practice in Diagnosis and Treatment Conference sponsored by Johns Hopkins Oncology Department, Baltimore, MD, September 30 - October 2, 1999.

2000

Sladek ML, Lally RM Swenson K, Ritz LJ. Research to Practice: Operationalizing the Breast Cancer Nurse Coordinator Role. Podium presentation at the Ninth Annual Nursing Research Conference held February 21, 2000, at the Mayo Clinic, Rochester, Minnesota.

Ritz LJ, Nissen MJ, Swenson KK, Farrell JB, Sperduto PW, Sladek ML, Lally RM, Schroeder LM. Effects of advanced nursing care on quality of life and cost outcomes of women diagnosed with breast cancer. Recipients of the 2000 Oncology Nursing Society/Schering Excellence in Cancer Nursing Research Award March 23, 2000.

Peden-McAlpine C, Ritz LJ, Brandt C, Fisbold M, Griebenow D, Swenson KK. Voices of women with breast cancer. Poster presentation at the meeting and abstract published in the DoD Breast Cancer Research Program, Era of Hope Meeting Proceedings, Atlanta, GA, June 8-11, 2000, Volume II:805.

Ritz LJ, Sperduto PW, Swenson KK. Effects of advanced nursing care on quality of life and cost outcomes of women diagnosed with breast cancer. Podium presentation at the Oncology Nursing Society 25th Annual Congress, May 11-14, 2000 in San Antonio, Texas.

Ritz LJ, Nissen MJ, Swenson KK, Farrell JB, Sperduto PW, Sladek ML, Lally RM, Schroeder LM. Effects of advanced nursing care on quality of life and cost outcomes of women diagnosed with breast cancer. *Oncology Nursing Forum*, July 2000, 27(6):1-10.

Ritz LJ, Sladek ML. Effects of advanced nursing care on QOL and cost outcomes of women newly diagnosed with breast cancer. Presentation at Ridgeview Hospital, Waconia, Minnesota, June 16, 2000.

Conclusions

Women with newly-diagnosed breast cancer have multiple needs requiring interventions. Uncertainty decreased significantly during the first 6 months after diagnosis for women who received the APN interventions in both the randomized clinical trial and the comparative study. The APN interventions significantly improved mood and well-being for unmarried women and improved well-being in women with no family history of breast cancer. Cost savings were not recognized in either the randomized trial or the follow-up study. However the costs of the APN intervention were decreased when further focusing and structuring the interventions.

The "so what" of these results is that they provide a strong research base on which to further determine care delivery for women with breast cancer. Subjective and objective factors must be considered when determining the effects of care delivery changes. These studies look at both, provide a model in which to pursue additional measurement of care delivery changes, and provide direction to changes that improve quality outcomes and are cost-effective.

Subsets of the data from these studies will be further analyzed and add to the body of knowledge to improve care of women diagnosed with breast cancer. Integration of components of the APN role and outcomes with those of other providers, utilizing the experiences of women with breast cancer, care delivery and health care policy change, and other methods of making the care of women with breast cancer both cost-effective and further improve QOL must be studied and clinically applied.

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Table 1: Standard APN Follow-Up Care

<u>Phase of Care</u>	<u>Intervention</u>	<u>Focus</u>
Introduction (Preoperative)	Assessment	Physical assessment General needs assessment
	Education	Availability of APN and role Consultation expectations Discussion on decision making
	Care Coordination	Follow-up plan of care Arrange multidisciplinary consults (Oncology , Radiation Oncology, Plastic Surgery) Presence at consultations
Postoperative	Assessment	Signs of postoperative complications <ul style="list-style-type: none"> • Bleeding, infection • Pain and nausea management • Swelling, inflammation, and redness <ul style="list-style-type: none"> • Wound care, dressing care • Drain • Lymphedema prevention/care Ability to cope with changes
	Education	Reinforce postoperative self-care Review of pathology report
	Care Coordination	Reach to Recovery/prosthesis Follow-up visits with surgeon(s)
Therapy	Assessment	Physical well-being (hospital/clinic/home) <ul style="list-style-type: none"> • Range of motion, seroma, necrosis • Oral intake Psychosocial well-being <ul style="list-style-type: none"> • Mood • Coping • Support <ul style="list-style-type: none"> • Understanding lab values • Energy level/fatigue
	Education	Local and systemic treatments <ul style="list-style-type: none"> • Radiation therapy • Chemotherapy • Hormonal therapy

Table 1: Standard APN Follow-Up Care (Cont.)

<u>Phase of Care</u>	<u>Intervention</u>	<u>Focus</u>
	Symptom Management	<ul style="list-style-type: none"> • Fatigue • Nausea/Vomiting • Constipation/Diarrhea • Mouth sores • Hair loss • Skin changes • Hot flashes
	Care Coordination	Arrange follow-up visits postoperatively Presence at follow-up visits
	Consultation & Referral	Social Services, mental health, physical therapy i.e. Community support groups
Post-Treatment Follow-up	Assessment	<ul style="list-style-type: none"> • Treatment recovery • Psychosocial needs/coping • Quality of life • Lymphedema prevention/care • Sexuality • Nutritional status • Activities of daily living
	Education	General health promotion Fatigue management Complementary therapies
	Care Coordination	Follow-up visits Mammograms

Table 2. Participant vs. Non-Participant Characteristics

Variable	n = 210* Participants	n = 347 Non-Participants	P - Value
Mean age at diagnosis (yr)	55.5	61.4	< 0.0001
Mean tumor size (cm)	2.0	2.2 (n = 292)	0.42
	n (%)	n (%)	
Age (yr)			< 0.0001
< 40	20 (9.5)	19 (5.5)	
40-49	49 (23.3)	66 (19.0)	
50-59	65 (31.0)	78 (22.5)	
60-69	47 (22.4)	58 (16.7)	
> 69	29 (13.8)	126 (36.3)	
Race			0.64
White	204 (97.1)	341 (98.3)	
Asian	3 (1.4)	4 (1.1)	
African American	2 (1.0)	2 (0.6)	
American Indian	1 (0.5)	0 (0.0)	
Marital Status			0.06
Single, never married	26 (12.4)	34 (9.8)	
Married	144 (68.5)	208 (59.9)	
Divorced	17 (8.1)	30 (8.7)	
Widowed	23 (11.0)	66 (19.0)	
Unknown	0 (0.0)	9 (2.6)	
Extent of disease (SEER Stage)			0.003
In situ	20 (9.5)	66 (19.0)	
Localized	114 (54.3)	186 (53.6)	
Regional	72 (34.3)	83 (23.9)	
Distant	4 (1.9)	12 (3.5)	
Histology			0.003
Non-invasive	20 (9.5)	66 (19.0)	
Invasive	190 (90.5)	281 (81.0)	
Broder's Grade			0.46
Grade 1, well differentiated	31 (14.8)	37 (10.7)	
Grade 2, moderately differentiated.	96 (45.7)	148 (42.6)	
Grade 3, poorly differentiated	74 (35.2)	128 (36.9)	
Grade 4, undifferentiated	9 (4.3)	9 (2.6)	
Unknown	0 (0.0)	25 (7.2)	

Table 2. Participant vs. Non-Participant Characteristics (Cont.)

Variable	n = 210 Participants	n = 347 Non-Participants	P - Value
Tumor size			0.80
< 2 cm	116 (55.2)	153 (44.1)	
2 - 5 cm	84 (40.0)	123 (35.4)	
> 5 cm	10 (4.8)	16 (4.6)	
Unknown	0 (0.0)	55 (15.9)	
No. of positive nodes			0.42
None	121 (57.6)	161 (46.4)	
1-3	45 (21.4)	42 (12.1)	
4-9	15 (7.2)	24 (6.9)	
> 9	11 (5.2)	12 (3.4)	
Not assessed	18 (8.6)	105 (30.3)	
Unknown	0 (0.0)	3 (0.9)	
Method of detection			0.10
Regular self exam	48 (22.9)	59 (17.0)	
Doctor	18 (8.6)	46 (13.3)	
Incidental by patient	36 (17.1)	43 (12.4)	
Mammogram	108 (51.4)	175 (50.4)	
Unknown	0 (0.0)	24 (6.9)	
Family history of breast cancer			0.10
Yes	51 (24.3)	94 (27.1)	
No	141 (67.1)	185 (53.3)	
Unknown	18 (8.6)	68 (19.6)	

* Initially, 211 women were randomized to the Intervention condition. One was restaged to a non-cancerous condition after enrolling and withdrew from the study. She is not included in this table.

Table 3. Patient Characteristics At Diagnosis

Variable	Intervention Group n = 106	Control Group n = 104	P - Value
Mean age (yr)	55.7	55.3	0.79
Mean years of education	14.1 (n=103)	14.3 (n=91)	0.61
Mean tumor size (cm)	2.0	2.1	0.57
Age (yr)	n (%)	n (%)	0.97
< 40	9 (8.5)	11 (10.6)	
40-49	24 (22.6)	25 (24.0)	
50-59	34 (32.1)	31 (29.8)	
60-69	25 (23.6)	22 (21.2)	
> 69	14 (13.2)	15 (14.4)	
Race			0.90
White	103 (97.2)	101 (97.0)	
Asian	2 (1.9)	1 (1.0)	
African American	1 (0.9)	1 (1.0)	
American Indian	0 (0.0)	1 (1.0)	
Marital Status			0.76
Single, never married	11 (10.4)	15 (14.4)	
Married	74 (69.8)	70 (67.3)	
Divorced	8 (7.5)	9 (8.7)	
Widowed	13 (12.3)	10 (9.6)	
Income			0.08
Below \$31,000	24 (22.6)	26 (25.0)	
\$31,000-50,999	22 (20.8)	22 (21.2)	
\$51,000-70,999	21 (19.8)	7 (6.7)	
\$71,000-90,999	11 (10.4)	17 (16.3)	
\$91,000 or more	18 (17.0)	14 (13.5)	
Not provided	10 (9.4)	18 (17.3)	
Insurance			0.68
HMO	60 (56.6)	53 (51.0)	
Non-HMO	22 (20.8)	26 (25.0)	
Medicare/Medical Assistance	24 (22.6)	25 (24.0)	

Table 4. Disease Status at Diagnosis

Variable	Intervention Group n = 106	Control Group n = 104	P -Value
Extent of disease (SEER Stage)			0.11
In situ	12 (11.3)	8 (7.7)	
Localized	49 (46.2)	65 (62.5)	
Regional	43 (40.6)	29 (27.9)	
Distant	2 (1.9)	2 (1.9)	
Histology			0.37
Non-invasive	12 (11.3)	8 (7.7)	
Invasive	94 (88.7)	96 (92.3)	
Broder's Grade			0.04
Grade 1, well differentiated	15 (14.2)	16 (15.4)	
Grade 2, moderately diff.	55 (51.9)	41 (39.4)	
Grade 3, poorly differentiated	29 (27.4)	45 (43.3)	
Grade 4, undifferentiated	7 (6.6)	2 (1.9)	
Tumor Size			0.47
< 2 cm	62 (58.5)	54 (51.9)	
2 - 5 cm	38 (35.8)	46 (44.2)	
> 5 cm	6 (5.7)	4 (3.9)	
No. of positive nodes			0.49
None	56 (52.8)	65 (62.5)	
1-3	26 (24.5)	19 (18.3)	
4-9	9 (8.5)	6 (5.8)	
> 9	6 (5.7)	5 (4.8)	
Not assessed	9 (8.5)	9 (8.6)	
Method of detection			0.47
Regular self exam	21 (19.8)	27 (26.0)	
Doctor	9 (8.5)	9 (8.6)	
Incidental by patient	22 (20.8)	14 (13.5)	
Mammogram	54 (50.9)	54 (51.9)	
Family history of breast cancer			0.34
Yes	46 (43.4)	52 (50.0)	
No	60 (56.6)	52 (50.0)	

Table 5. Breast Cancer Treatment

Variable	Intervention Group n = 106	Control Group n = 104	P - Value
Definitive Surgical Treatment			0.34
Mastectomy	49 (46.2)	55 (52.9)	
Lumpectomy	57 (53.8)	49 (47.1)	
Radiation Therapy			0.17
Yes	68 (64.2)	57 (54.8)	
No	38 (35.8)	47 (45.2)	
Chemotherapy			0.41
Yes	46 (43.4)	51 (49.0)	
No	60 (56.6)	53 (51.0)	
Reconstruction			0.21
Yes	18 (17.0)	25 (24.0)	
No	88 (83.0)	79 (76.0)	
Hormone Therapy			0.03
Yes	62 (58.5)	45 (43.3)	
No	44 (41.5)	59 (56.7)	

TABLE 6. Number Of Cases In Intervention And Control Groups According To Treatment

Treatment	Intervention	Control
Lumpectomy + RT*	26	20
Lumpectomy + CT*	0	1
Lumpectomy + RT + CT	12	13
Mastectomy	8	13
Mastectomy + CT	7	8
Mastectomy + RT + CT	10	3
Mastectomy + Reconstruction	6	5
Mastectomy + CT + Reconstruction	7	8
Mastectomy + RT + Reconstruction	1	0
Mastectomy + RT + CT + Reconstruction	1	3

*RT= radiation therapy; CT = chemotherapy.

Table 7. Cases in Intervention and Control Groups Completing QOL Questionnaires At Each Time Period

Time Period	Intervention n (%)	Control n (%)	P Value
Baseline	101 (95.3)	89 (85.6)	0.008
1 month	99 (93.4)	85 (81.7)	0.005
3 months	97 (91.5)	81 (77.9)	0.003
6 months	92 (86.8)	73 (70.2)	0.002
12 months	84 (79.2)	65 (62.5)	0.004
18 months	83 (78.3)	55 (52.9)	< 0.001
24 months	81 (76.4)	54 (51.9)	< 0.001

Table 8. Distribution Of Charges and Reimbursements (dollars) for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period.

	Intervention	Control	P – Value*
Overall Charges			0.128
Mean	34,100	32,399	
Median	29,506	26,079	
Range	12,020 – 109,591	9,149 – 141,734	
Standard Deviation	19,245	25,481	
Overall Reimbursement			0.305
Mean	23,946	23,476	
Median	18,713	18,460	
Range	6,361 – 70,467	4,071 – 114,998	
Standard Deviation	14,510	20,149	
Categories of Charges			
Inpatient			0.336
Mean	12,336	11,979	
Median	8,889	8,078	
Outpatient/Clinic			0.197
Mean	21,587	20,116	
Median	19,482	18,474	
Home Care			0.233
Mean	52	149	
Median	0	0	
ER/UrgentCare			0.120
Mean	125	156	
Median	0	46	
Categories of Reimbursement			
Inpatient			0.425
Mean	8,319	8,130	
Median	5,104	4,583	
Outpatient/Clinic			0.430
Mean	15,498	15,130	
Median	13,218	12,715	
Home Care			0.246
Mean	39	118	
Median	0	0	
ER/UrgentCare			0.142
Mean	90	99	
Median	0	36	

*By Wilcoxon-Mann-Whitney test.

Table 9. Length of Stay for Definitive Surgery and Later Admissions; Number of Inpatient, Outpatient/Clinic, Home Care, and ER/Urgent Care Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period.

	Intervention	Control	P Value*
Length of Stay for Definitive Surgery (Hours)			0.303
Mean	37	39	
Median	28	31	
Length of Stay for All Inpatient Admissions Following Definitive Surgery (Days)			0.364
Mean	2	1	
Median	0	0	
Number of Visits Overall			0.500
Mean	69	67	
Median	66	65	
Inpatient			0.205
Mean	1	1	
Median	1	1	
Outpatient/ Clinic			0.409
Mean	67	64	
Median	64	63	
Home Care			0.245
Mean	0	1	
Median	0	0	
ER/UrgentCare			0.097
Mean	1	1	
Median	0	0	

*By Wilcoxon-Mann-Whitney test.

Table 10. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Age.

	Intervention	Control	P – Value*
Number of cases			0.759
< 40 years	6	6	
40-49 years	20	16	
50-59 years	22	26	
60-69 years	21	15	
> 69 years	9	11	
Overall Charges (dollars)			
< 40 years			0.423
Mean	46,609	51,584	
Median	46,475	35,138	
40-49 years			1.000
Mean	36,304	35,657	
Median	33,593	33,154	
50-59 years			0.508
Mean	34,759	38,901	
Median	23,573	31,551	
60-69 years			0.008
Mean	31,374	19,739	
Median	24,133	19,203	
> 69 years			0.063
Mean	25,615	19,094	
Median	23,782	18,325	
Overall Reimbursement (dollars)			
< 40 years			0.109
Mean	36,307	38,572	
Median	35,844	25,352	
40-49 years			1.000
Mean	27,593	26,122	
Median	26,489	23,836	
50-59 years			0.255
Mean	25,199	30,403	
Median	17,541	22,256	
60-69 years			0.001
Mean	20,472	11,638	
Median	16,349	11,306	
> 69 years			0.621
Mean	12,644	11,164	
Median	11,556	10,108	

Table 10. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Age (Cont.)

	Intervention	Control	P Value*
Number of Visits			
< 40 years			0.199
Mean	94	81	
Median	98	76	
40-49 years			0.679
Mean	70	64	
Median	69	64	
50-59 years			0.569
Mean	65	76	
Median	62	67	
60-69 years			0.241
Mean	66	55	
Median	64	49	
> 69 years			0.425
Mean	65	59	
Median	64	53	

*By chi-square for number of cases; by Wilcoxon-Mann-Whitney test for charges, reimbursements and number of visits.

Table 11. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Marital Status.

	Intervention	Control	P – Value*
Number of cases			0.321
Not married	28	21	
Married	50	53	
Overall Charges (dollars)			
Not married			0.151
Mean	34,469	26,794	
Median	29,469	22,462	
Married			0.316
Mean	33,894	34,620	
Median	29,506	27,434	
Overall Reimbursement (dollars)			
Not married			0.233
Mean	24,576	18,400	
Median	17,201	16,318	
Married			0.649
Mean	23,593	25,487	
Median	19,065	18,816	
Number of Visits			
Not married			0.793
Mean	69	67	
Median	69	66	
Married			0.541
Mean	69	67	
Median	63	64	

*By chi-square for number of cases; by Wilcoxon-Mann-Whitney test for charges, reimbursements, and number of visits.

Table 12. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Extent Of Disease.

	Intervention	Control	P – Value*
Number of cases			0.145
In situ	6	5	
Localized	36	46	
Regional	35	21	
Distant	1	2	
Overall Charges (dollars)			
In situ			0.855
Mean	26,727	26,785	
Median	24,919	27,947	
Localized			0.654
Mean	26,324	26,426	
Median	22,879	21,498	
Regional			0.537
Mean	42,138	41,001	
Median	34,007	34,271	
Distant			— —
Mean	76,940	93,494	
Median	76,940	93,494	
Overall Reimbursement (dollars)			
In situ			0.855
Mean	17,954	18,667	
Median	18,298	18,524	
Localized			0.661
Mean	18,338	18,912	
Median	16,239	16,135	
Regional			0.767
Mean	29,609	29,403	
Median	23,577	24,145	
Distant			— —
Mean	63,582	78,239	
Median	63,582	78,239	

Table 12. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Extent Of Disease (Cont.)

	Intervention	Control	P Value*
Number of Visits			
In situ			0.927
Mean	47	47	
Median	54	44	
Localized			0.306
Mean	56	64	
Median	58	61	
Regional			0.125
Mean	86	75	
Median	85	72	
Distant			— —
Mean	75	94	
Median	75	94	

*By Fisher's exact test for number of cases; by Wilcoxon-Mann-Whitney test for charges, reimbursements, and number of visits.

Table 13. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups for the 2-Year Study Period. By Participation in Cancer Treatment Trials.

	Intervention	Control	P Value*
Number of cases			0.102
Nonparticipant	67	70	
Participant	11	4	
Overall Charges (dollars)			
Nonparticipant			0.186
Mean	32,518	32,379	
Median	27,794	25,336	
Participant			0.602
Mean	43,740	32,757	
Median	32,627	30,329	
Overall Reimbursement (dollars)			
Nonparticipant			0.552
Mean	22,449	23,426	
Median	17,208	18,069	
Participant			0.433
Mean	33,063	24,358	
Median	26,200	23,084	
Number of Visits			
Nonparticipant			0.867
Mean	66	67	
Median	64	65	
Participant			0.240
Mean	85	65	
Median	84	67	

*By Fisher's exact test for number of cases; by Wilcoxon-Mann-Whitney test for charges, reimbursements, and number of visits.

Table 14. Distribution of Charges, Reimbursements, and Number of Visits for Intervention (n = 78) and Control (n = 74) Groups For The 2-Year Study Period. By Survival Status While On Study.

	Intervention	Control	P – Value*
Number of cases			0.327
Alive w/o Recurrence	71	72	
Alive w/ Recurrence	4	1	
Died	3	1	
Overall Charges (dollars)			0.257
Alive w/o Recurrence			
Mean	31,157	30,876	
Median	26,310	25,336	
Alive w/ Recurrence			
Mean	49,593	48,820	
Median	46,984	48,820	
Died			
Mean	83,106	125,683	
Median	78,461	125,683	
Overall Reimbursement (dollars)			0.542
Alive w/o Recurrence			
Mean	21,622	22,248	
Median	17,194	18,069	
Alive w/ Recurrence			
Mean	34,307	41,479	
Median	29,018	41,479	
Died			
Mean	65,127	93,860	
Median	63,582	93,860	
Number of Visits			0.842
Alive w/o Recurrence			
Mean	66	65	
Median	64	64	
Alive w/ Recurrence			
Mean	102	72	
Median	104	72	
Died			
Mean	109	226	
Median	94	226	

* By Fisher's exact test for number of cases; by Wilcoxon-Mann-Whitney test for charges, reimbursements, and number of visits.

Table 15. Distribution of APN Time and Cost Per Patient According To Type of Service

APN Service	Mean APN Time / Patient (minutes)	Mean Cost of Service / Patient
Overall	1,377	\$629
Clinic Visits	683	\$307
Hospital Visits	83	\$37
Telephone Visits	368	\$166
Home Care Visits	55	\$34*
Administrative	188	\$85

*Includes mileage of \$0.315/mile for travel to and from the appointments.

Table 16. Study 2 Participant Characteristics

Variable	n = 47
Mean age at diagnosis (yr)	55.7
Mean years of education	14.2 (n = 46)
Mean tumor size (cm)	1.6
	n (%)
Age (yr)	
< 40	4 (8.5)
40-49	10 (21.3)
50-59	14 (29.8)
60-69	11 (23.4)
> 69	8 (17.0)
Race	
White	46 (97.9)
Asian	0 (0.0)
African American	0 (0.0)
American Indian	1 (2.1)
American Indian	1 (2.1)
Marital Status	
Single, never married	6 (12.8)
Married	28 (59.5)
Divorced	7 (14.9)
Widowed	6 (12.8)
Income	
Below \$31,000	11 (23.4)
\$31,000-50,999	6 (12.8)
\$51,000-70,999	17 (36.2)
\$71,000-90,999	3 (6.4)
\$91,000 or more	5 (10.6)
Not provided	5 (10.6)
Insurance	
HMO	24 (51.1)
Non-HMO	12 (25.5)
Medicare/Medical Assistance	11 (23.4)
Extent of disease (SEER Stage)	
In situ	4 (8.5)
Localized	32 (68.1)
Regional	11 (23.4)
Distant	0 (0.0)

Table 16. Study 2 Participant Characteristics (Cont.)

Histology	
Non-invasive	4 (8.5)
Invasive	43 (91.5)
Broder's Grade	
Grade 1, well differentiated	6 (12.8)
Grade 2, moderately diff.	24 (51.0)
Grade 3, poorly differentiated	17 (36.2)
Grade 4, undifferentiated	0 (0.0)
Tumor Size	
< 2 cm	25 (53.2)
2 – 5 cm	14 (29.8)
> 5 cm	1 (2.1)
Unknown	7 (14.9)
No. of positive nodes	
None	32 (68.1)
1-3	7 (14.9)
4-9	3 (6.4)
> 9	1 (2.1)
Not assessed	4 (8.5)
Method of diagnosis	
Regular self exam	2 (4.3)
Doctor	0 (0.0)
Incidental by patient	11 (23.4)
Mammogram	31 (65.9)
Unknown	3 (6.4)
Family history of breast cancer	
Yes	10 (21.3)
No	37 (78.7)
Definitive Surgical Treatment	
Mastectomy	18 (38.3)
Lumpectomy	29 (61.7)

Table 17. Comparison of Mean Time/Patient and Mean Cost of Service Between Phase I and Phase II (Shaded).

APN Service	Phase I Mean APN Time/Patient - first 6 months (minutes)	Phase II Mean APN Time/Patient (minutes)	Phase I Mean Cost of Service/Patient – first 6 months	Phase II Mean Cost of Service/Patient
Clinic Visits	419	217	\$189	\$98
Hospital Visits	46	19	\$21	\$9
Telephone Visits	164	153	\$74	\$69
Home Care Visits	32	10	*\$19	*\$5
Administrative Time	86	58	\$39	\$26
Overall / Patient	747	457	\$342	\$207

*Includes mileage of \$0.315/mile for travel to and from the appointments.

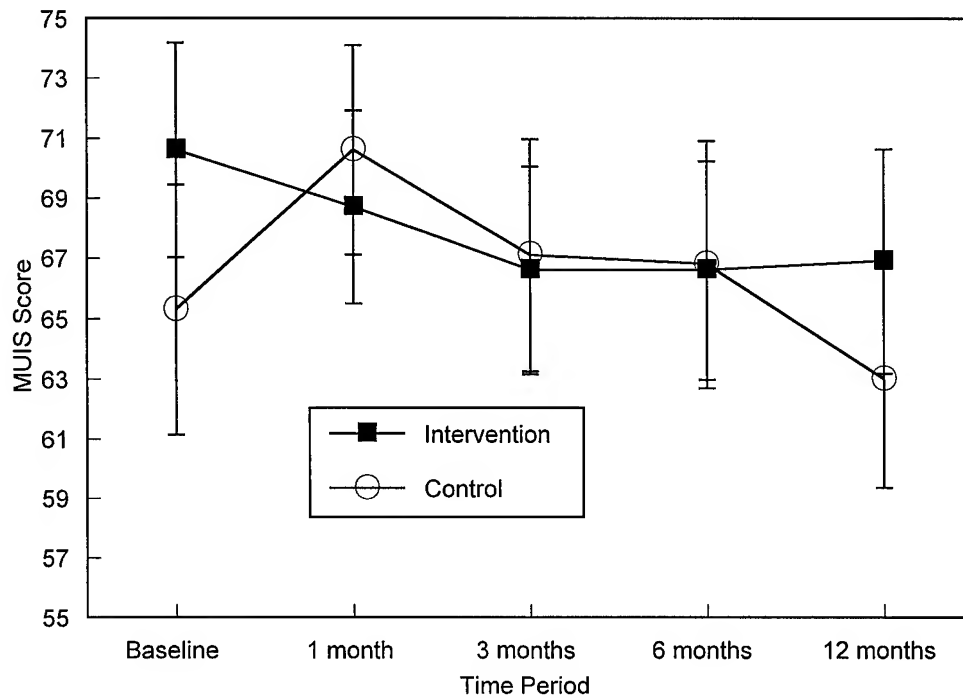


Figure 1. Mean MUIS scores with 95% confidence limits for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater uncertainty.

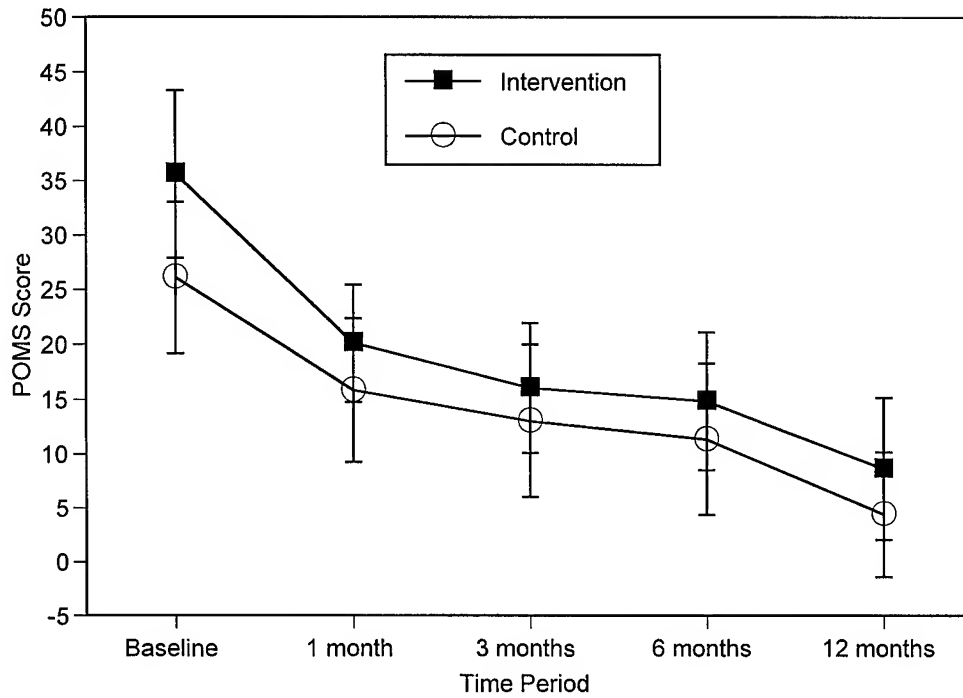


Figure 2. Mean POMS scores with 95% confidence limits for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater mood disturbance.

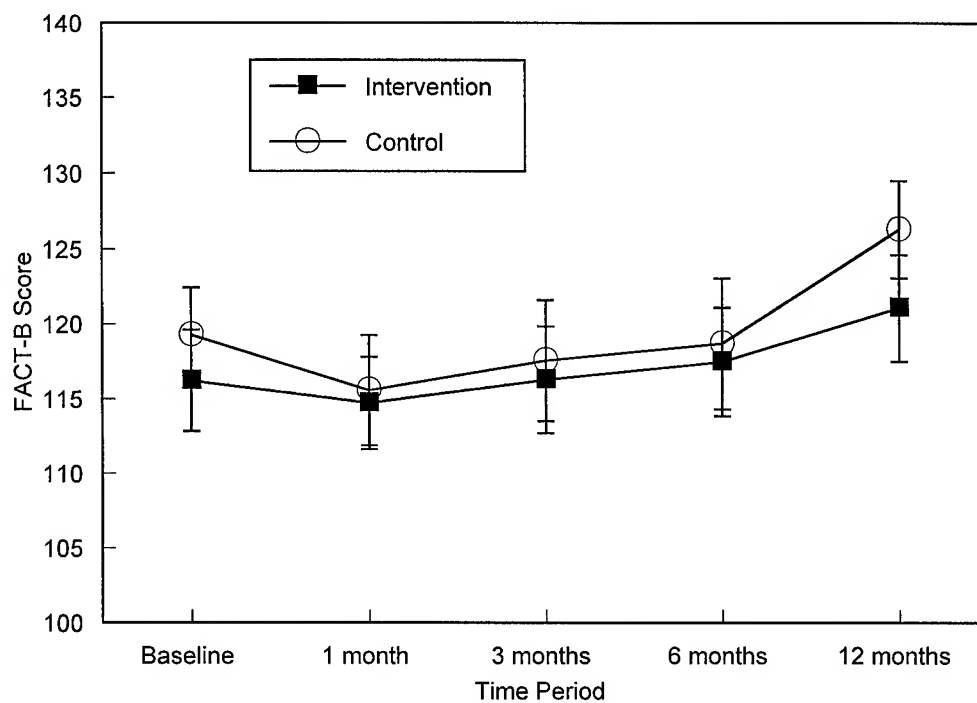


Figure 3. Mean FACT-B scores with 95% confidence limits for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater well-being.

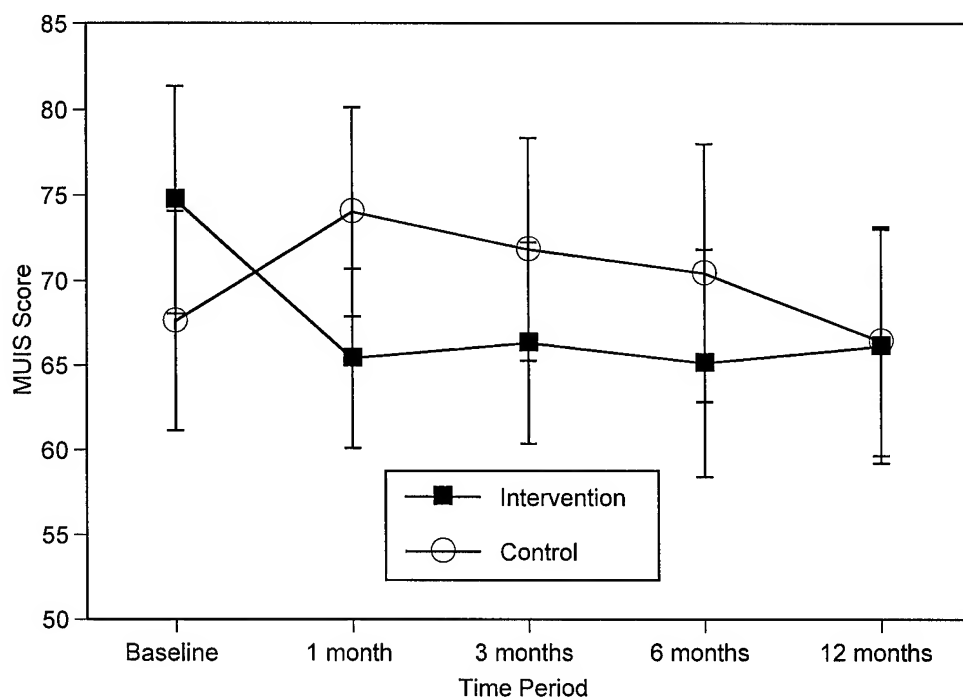


Figure 4. Mean MUIS scores with 95% confidence intervals for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater uncertainty. UNMARRIED CASES ONLY.

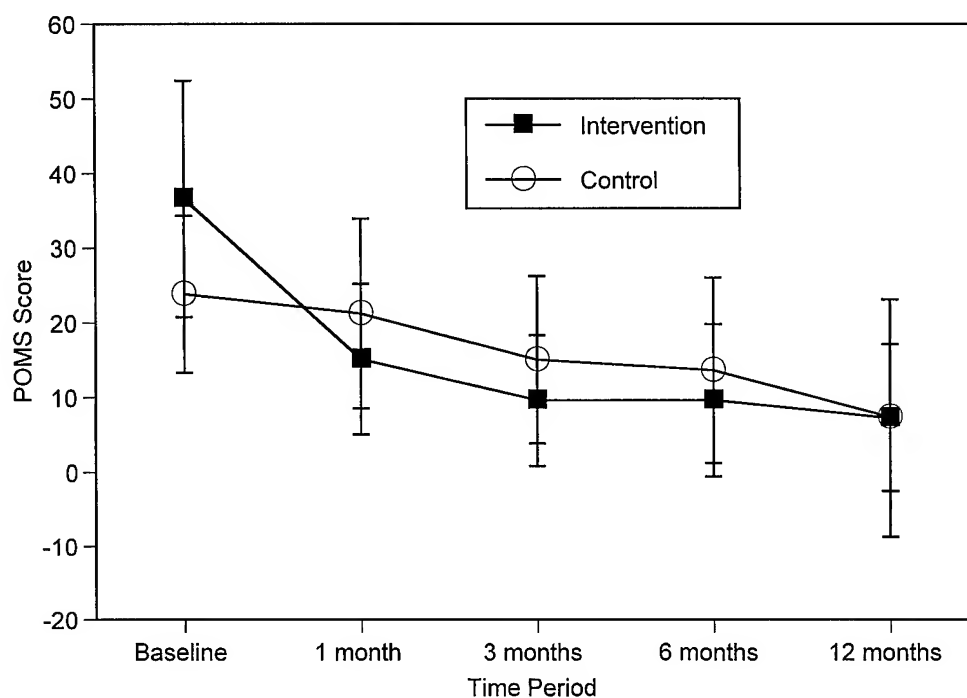


Figure 5. Mean POMS scores with 95% confidence limits for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater mood disturbance. UNMARRIED CASES ONLY.

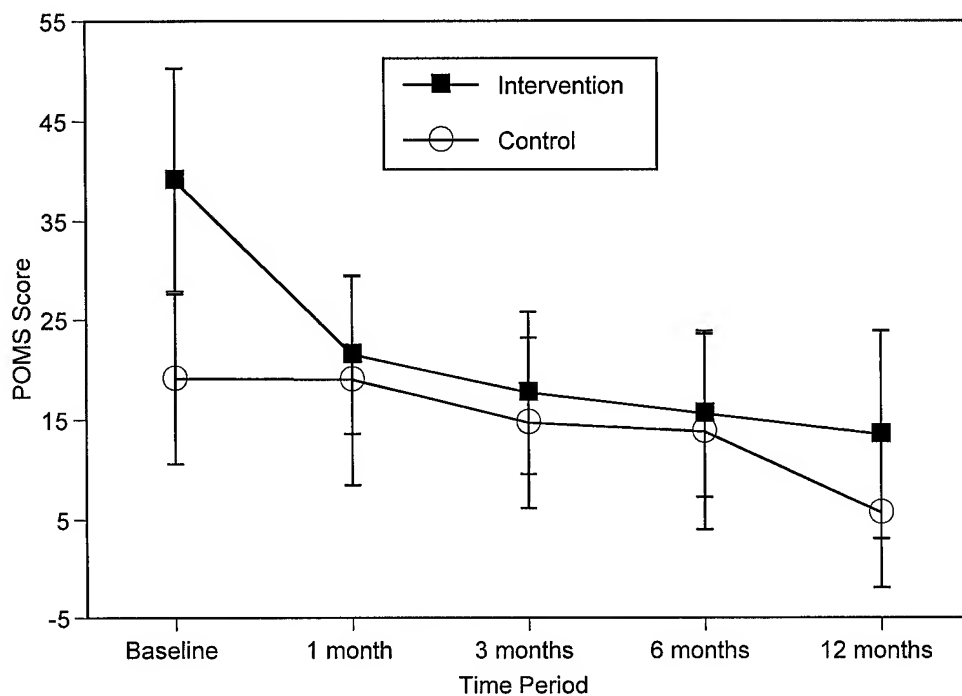


Figure 6. Mean POMS scores with 95% confidence limits for intervention and control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater mood disturbance. WOMEN WITH NO FAMILY HISTORY OF BREAST CANCER ONLY.

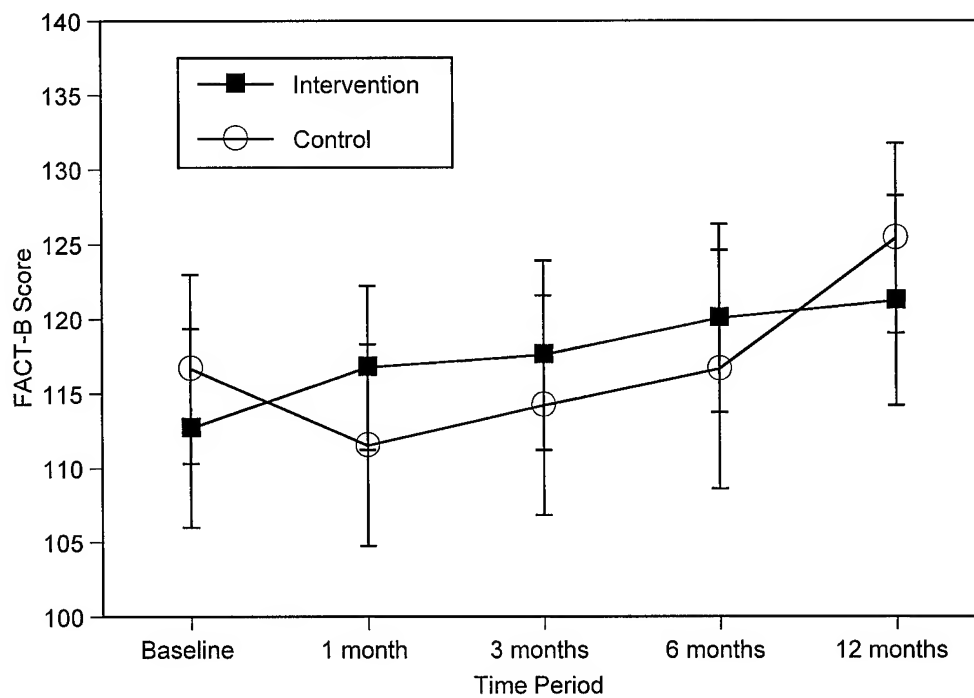


Figure 7. Mean FACT-B scores with 95% confidence limits for Intervention and Control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater well-being. UNMARRIED CASES ONLY.

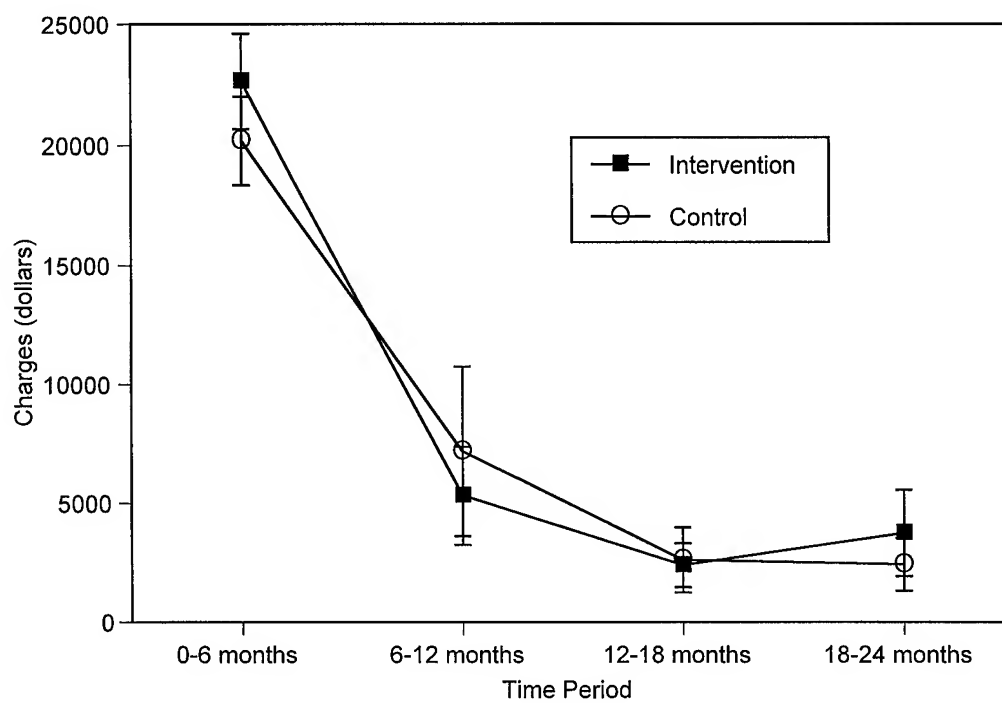


Figure 8. Mean charges (in dollars) with 95% confidence limits for Intervention and Control groups during four time periods..

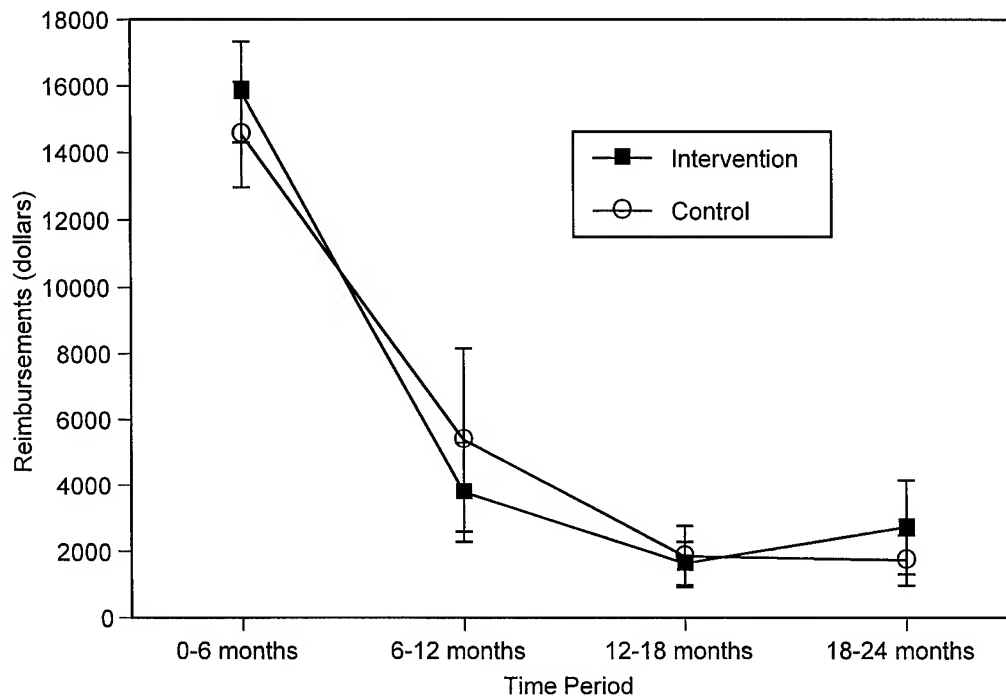


Figure 9. Mean reimbursements (in dollars) with 95% confidence limits for Intervention and Control groups during four time periods.

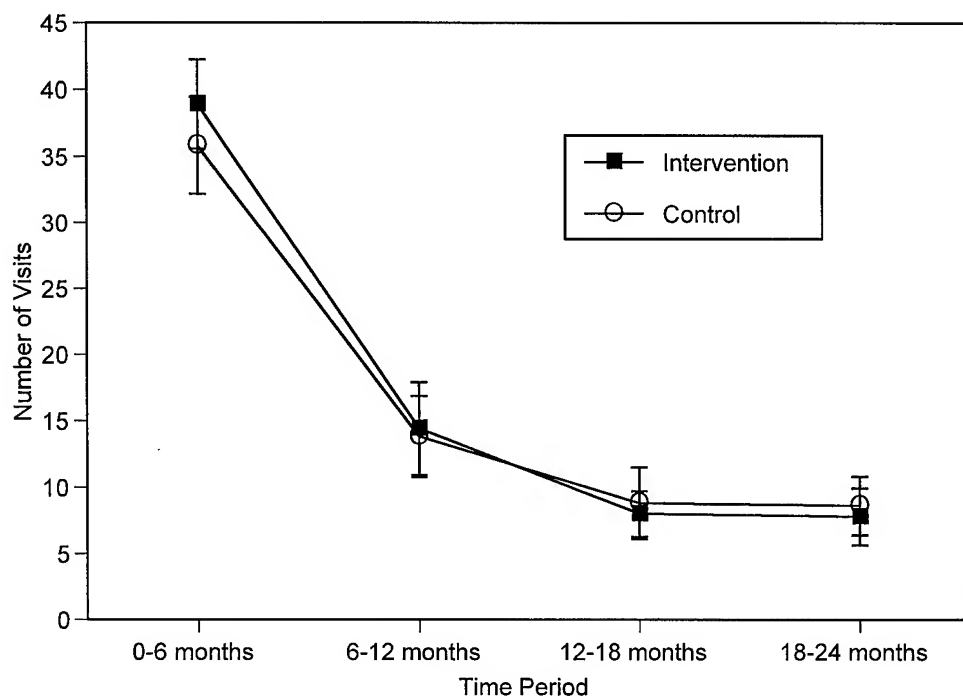


Figure 10. Mean number of healthcare visits, with 95% confidence limits, for Intervention and Control groups during four time periods.

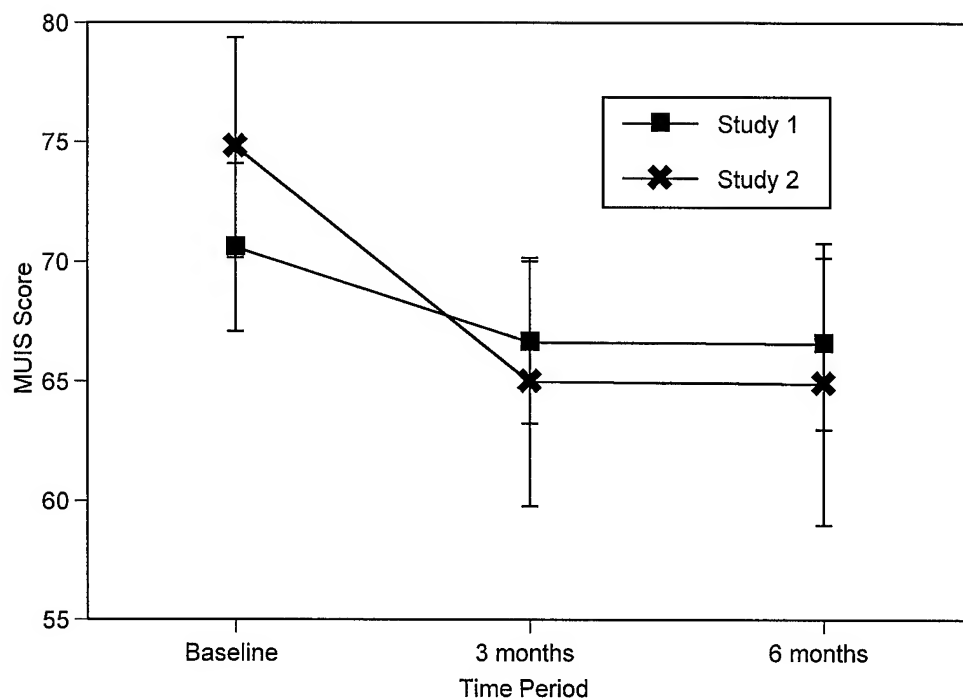


Figure 11. Mean MUIS scores with 95% confidence limits for Study 1 and Study 2 Intervention groups at baseline and at 3 and 6 months following baseline. Higher scores indicate greater uncertainty.

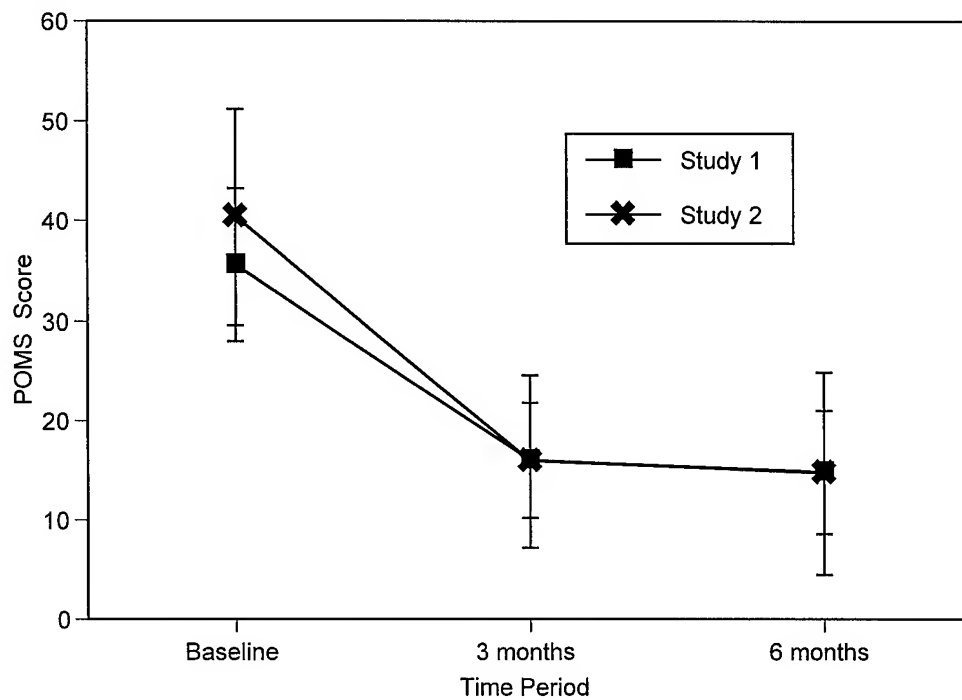


Figure 12. Mean POMS scores with 95% confidence limits for Study 1 and Study 2 Intervention groups at baseline and at 3 and 6 months following baseline. Higher scores indicate greater mood disturbance.

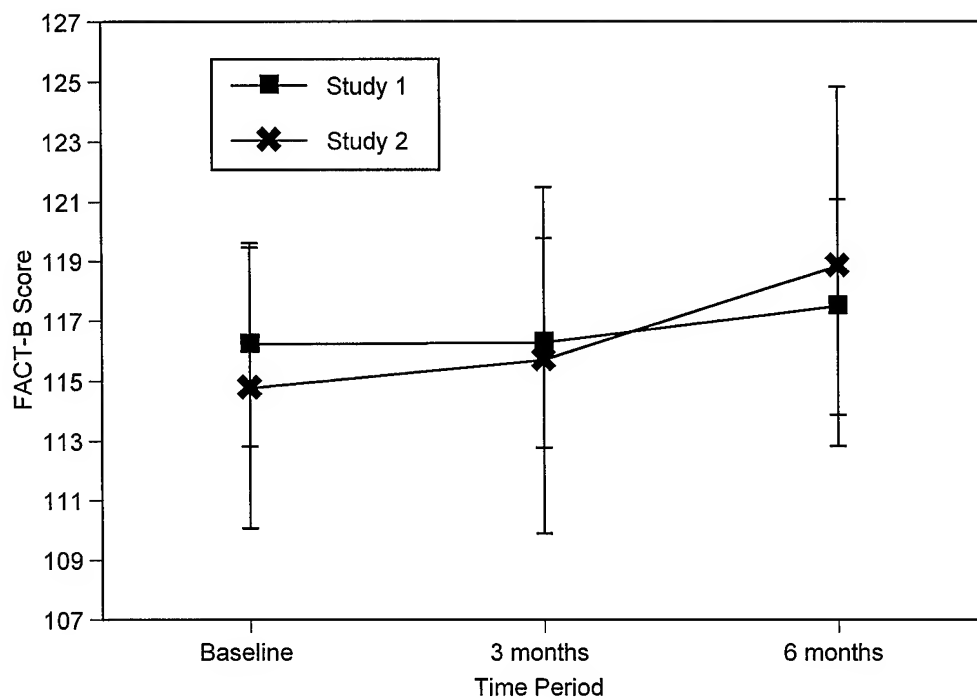


Figure 13. Mean FACT-B scores with 95% confidence limits for Study 1 and Study 2 Intervention groups at baseline and at 3 and 6 months following baseline. Higher scores indicate greater well-being.

Poster Presentation at the University of Chicago Hospitals 10th Annual Nursing Research Symposium, "Advancing Nursing Practice: Emerging Roles and Clinical Outcomes," November 17, 1995

Evaluation of the Breast Cancer Nurse Coordinator:
Utilizing Presence in Advanced Practice
Lynne Schroeder, Mary Geditz

The Breast Cancer Nurse Coordinator (BCNC) role demonstrates an innovative model for the advanced practice nurse. The purpose of this model is to explore the dilemma of the breast cancer patient, introduce the role of the BCNC, propose presence as the ideal intervention and describe potential clinical outcomes. Women with breast cancer face multiple challenges: confronting fears about a life-threatening diagnosis, seeking information about treatment options, facing uncertainty while making a series of critical decisions and alteration in lifestyle. Typical responses include anxiety, fear, helplessness, hopelessness and depression, anger and denial (Hughes, 1991, Poncar, 1991). In this model, BCNC interventions include: coordination, direct care, education, consultation, research and administration. Activities involve guiding patients through the health care system, collaborating in interdisciplinary care, serving as patient advocate, assessing physical, psychosocial and educational needs, presenting information, facilitating communication and offering emotional support. The use of presence as a intervention is indispensable in producing a significant therapeutic effect. (Kleiman, 1993; Wagner, 1994; Watson, 1988). Presence is a subjective exchange with thoughts, feelings or beliefs that involve sensory stimulation, imagination, memory and intuition, involving verbal and nonverbal communication (Gilje & Gardner, 1985). Requiring both personal and professional levels of commitment, presence includes understanding, empathy, attentive listening, trust and availability. It is accountable, goal-directed and individualized to each patient (Paterson & Zderad, 1988). Based on Egan's Helping Model (Egan, 1982), the conceptual framework illustrates an interactive process involving the patient and the BCNC. Problems are clarified and coping mechanisms are identified. Potential clinical outcomes may be measured by changes in the following variables: (a) cognitive, i.e. increased understanding of cancer/treatment side effects and decision-making ability; (b) physical, i.e. enhanced comfort level and decreased disease/treatment side effects; (c) behavioral, i.e., promotion of health maintenance/treatment compliance and independence in self-care; (d) psychosocial, i.e. augmented coping skills, decreased uncertainty/anxiety levels and promotion of quality of life. Preventing unnecessary admissions, decreasing rate of complications and length of the hospital stay may impact cost of care. Ultimately, patient outcomes can be measured by prevention of injury, reintegration of patient to employment/community activities, and satisfaction with the health care system. (Smith & Waltman, 1994, Hutchens, 1994, Gibson et al, 1994, and Moritz, 1991). This model of management of breast cancer patients provides a prototype for the Advance Practice Nurse role in the clinical setting. Measurement of clinical outcomes and cost savings should demonstrate the effectiveness of this evolving role.

Poster presentation at the 21st Annual Congress of the Oncology Nursing Society,
Philadelphia, PA, May 2-5, 1996.

**DEVELOPING A CRITICAL PATHWAY EARLY DISCHARGE FOLLOWING BREAST
CANCER SURGERY UTILIZING THE BREAST CANCER NURSE COORDINATOR.**

Mary Geditz, RN, MS and Lynne Schroeder, RN, MS (cand), BSN, Methodist Hospital
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With the growing concern of health care costs, managed care has flourished as a health care delivery system offering cost-effective and quality patient care. Critical pathways link quality patient care to outcomes and serve as a guideline to systematically move the patient from admission to discharge as the patient meets specific criteria. Surgical procedures such as modified radical mastectomy with axillary dissection and partial mastectomy with axillary dissection follow a similar pattern of hospitalization for breast cancer surgery. Studies demonstrate that discharge on the first post-op day does not endanger patient safety or result in an increase in readmissions; it may even improve psychological outlook. The Breast Cancer Nurse Coordinator (BCNC) at Methodist Hospital, is an innovative model for the advanced practice nurse and initiates the critical pathway for early discharge of the breast cancer patient. In an effort to improve upon the 52% (n= 130) of 1995 breast surgical patients at Methodist Hospital currently being discharged in 24 hours, the BCNC meets the patient at the time of their breast cancer diagnosis and assesses obstacles to early discharge, i.e. functional status, coping ability, adequate social support, and/or caregiving involvement. Pre-operatively all patients meet with the surgeon, oncologist, and radiation therapist and reach a multi-disciplinary decision regarding treatment. Once surgery is scheduled, both pre and post-operative education is begun. Educational criteria for early discharge include patients and families demonstrating the ability to care for suction drains and wound dressings; to understand signs and symptoms of infection, bleeding, and unusual swelling; to manage pain, nausea and vomiting; to anticipate follow-up doctor and home care visits, exercise regimen, mobility limitations and transportation needs. An uncomplicated surgery begins the second step of the pathway; post-operative parameters include stable vital signs, mental alertness and orientation, pain control, oral intake, voiding and ambulation with no evidence of bleeding, nausea, vomiting, and dizziness. The BCNC makes follow-up home visits and daily telephone calls to further assess for post-op complications and decrease anxiety. Potential clinical outcomes are measured by increased autonomy, self care behaviors, enhanced comfort level, decreased anxiety levels, and avoidance of readmission to the acute care facility. Continuation of the relationship with the BCNC ensures evaluation of outcomes and promotes patient safety and satisfaction with care.

Poster Presentation at the University of Chicago Hospitals 11th Annual Nursing Research Symposium, "The Scope of Nursing Practice in a Changing Healthcare Environment," Chicago, IL, November 15, 1996.

EARLY DISCHARGE FOLLOWING BREAST CANCER SURGERY: UTILIZING HOME CARE NURSES IN THE SURGICAL SETTING. Mary Sladek, RN, MS, OCN (612) 993-5751 and Lynne Schroeder, RN, MS (cand), BSN, OCN (612) 993-6030
Oncology Research, Institute for Research and Education, Methodist Hospital Cancer Center, HealthSystem Minnesota, Minneapolis, MN 55440

Recent trends in health care delivery transfer breast cancer surgery from inpatient to outpatient settings. This cost containment effort generated an innovative model of nursing practice designed to maintain quality patient care with limited time constraints (Moritz, 1991). Women undergoing partial or modified radical mastectomies are a potentially vulnerable patient population. Patient and family must contend with stresses of surgery and recovery along with a new diagnosis of cancer. Historically, women were hospitalized for 24-72 hours; however, current practice is to send patients home 8 to 24 hours after surgery. Studies show conflicting evidence about effects of early discharge on breast cancer patients (Ruckley, 1980). It promotes increased independence, decreased narcotic use and enhanced outlook concerning convalescence (Goodman & Mendez, 1993). Because early discharge reduces time spent in health care settings, there are fewer educational opportunities resulting in poor information dissemination and inadequate time to ask questions (Hawkshaw, 1994). Decreased time in-hospital may also eliminate professional support, add caregiver burden and allow for undetected post-op complications. According to McCorkle (1994), patients are psychosocially in crisis after surgery for primary treatment of cancer. Crisis states are measured by high levels of symptom distress, limited self-care and functional abilities as well as poor health perceptions. Realizing the potential negative effects of early discharge on patients, health care facilities are improving protocols. Pre-assessment clinics, 24-hour post-op telephone calls, and post-op home care visits are being implemented (Hawkshaw, 1994). Post-op phone calls alone are insufficient interventions for positive patient outcomes (American Health Consultants, 1995). Functional ability of the caregiver and patient in the home setting needs evaluation. McCorkle (1994) demonstrates that home care can improve patient outlook after cancer treatment and hospitalization. At Methodist Hospital, HealthSystem Minnesota (MH/HSM), home care nurses are incorporated in the critical pathway and offer both pre-operative and post-operative visits for breast cancer patients undergoing same day surgery. Visits include assessment of patient/caregiver's functional status, surgical education, and psychosocial support. MH/HSM cost analysis illustrates a >50% cost savings with same day surgery versus general hospital admission for breast cancer surgery. Home care costs less than an inpatient admission and provides needed after-care, education and psychosocial support. Utilization of home care nurses maximize positive clinical outcomes, e.g. improves quality of life, broadens knowledge base, assures physical comfort, increases safety and decreases anxiety. Anticipating concerns and exceeding expectations about early discharge will promote positive outcomes.

- Poster presentation at the 4th National Conference on Cancer Nursing Research, Panama City, FL, January 23-25, 1997

COST ANALYSIS OF BREAST CANCER SURGERY: OUTPATIENT SURGERY VERSUS HOSPITAL ADMISSION

Mary Sladek, RN, MS, OCN and Lynne Schroeder, RN, MS (c), OCN, Oncology Research, Institute for Research and Education, Methodist Hospital Cancer Center, HealthSystem Minnesota, Minneapolis, Minnesota

Three hundred and eighteen women were diagnosed with breast cancer in 1995 in a Midwest community health care facility; 96% had either lumpectomy or modified radical mastectomy. Historically, patients were hospitalized for 1 to 3 days. However, practice patterns have changed with cost containment mandating reduced hospital stays. Research has shown that the outpatient setting with same day discharge is safe for women undergoing breast cancer surgery. Theoretically, cost reduction should result for both patient and health care system. The purpose of this retrospective pilot study is to compare age, comorbid disease and cost of care for outpatient admission versus hospital admission in a managed care setting.

A convenience sample of 32 consecutive cases was selected: 17 hospital admissions (HA) with an expected overnight stay, 15 outpatient (OP) to be discharged in ≤ 10 hours. Eligibility criteria included subtotal mastectomy with axillary dissection and ≤ 1 day stay. Charge data and chart audits determined cost and surgical outcomes; age and comorbidity were also analyzed. Three OP cases required overnight stays (OS) due to complications, e.g., nausea, pain and sedation. Average age for groups were: HA=62 years (range 40-83), OP = 58 years (range 37-77), OS = 70 years (range 56-81). Average hospital charges were \$4,909 for HA, \$1,234 for OP and \$1,872 for OS. Analysis demonstrated a 4 times greater expense for the HA group due to costs of surgical procedure, surgical suite, and recovery room. The OP group had only a single charge for the surgical procedure, reflecting the cost savings for this group. Even with overnight stay (>10 hours) cost savings were 2.5 times greater for the OS group than the HA group. Comorbid disease had minimal impact on admission status between the groups; however, notable history included MI, angina and depression for 3 of the 17 cases in the HA group. Hypertension, arthritis and smoking were common in all groups. HA and OP groups were of similar age; those that required extended (overnight) stay post-operatively were older.

Outpatient surgery is reasonable for patients regardless of comorbid disease; age may necessitate extended stay. Simply changing mode of admission from hospital to outpatient may offer substantial financial savings to both patient and health care delivery system. Expanding nursing roles to manage pre-op assessment, mandate caregiver education and endorse self-care regimens, will nurture positive outcomes in the outpatient setting.

- Podium Presentation at the 22nd Annual Congress of the Oncology Nursing Society, New Orleans, LA, May 1-4, 1997.

COST COMPARISON OF BREAST CANCER SURGERY: OUTPATIENT SURGERY VERSUS HOSPITAL ADMISSION. Mary Sladek, RN, MS, OCN and Lynne Schroeder, RN, MS (c), OCN, Oncology Research, Institute for Research and Education Methodist Hospital Cancer Center, HealthSystem Minnesota, Minneapolis, MN 55440 and Laurie Ritz, RN, MSN, OCN, Methodist Hospital, HealthSystem Minnesota, Minneapolis, MN 55440

Three hundred and eighteen women were diagnosed with breast cancer in 1995 in a Midwest community health care facility; 96% had either lumpectomy or modified radical mastectomy. Historically, patients were hospitalized for 1 to 3 days. However, practice patterns have changed with cost containment mandating reduced hospital stays thus altering the way nursing care must be delivered. Research has shown that the outpatient setting with same day discharge is safe for women undergoing breast cancer surgery. In this managed care setting as an advanced practice nursing (APN) project,* a retrospective pilot study was initiated to compare age, comorbid disease and cost of care for outpatient admission versus hospital admission. A convenience sample of 32 consecutive cases was selected: 17 hospital admissions (HA) with an expected overnight stay and 15 outpatients (OP) discharged in ≤ 10 hours. Eligibility criteria included subtotal mastectomy with axillary dissection and ≤ 1 day stay. Charge data and chart audits determined cost and surgical outcomes; age and comorbidity were also considered. Three OP cases required overnight stay (OS) due to complications, e.g., nausea, pain and sedation. Average age for groups were: HA = 62 years (range 40-83), OP = 58 years (range 37-77), OS = 70 years (range 56-81). Average hospital charges were \$4,909 for HA, \$1,234 for OP and \$1,872 for OS. A four times greater expense for the HA group was due to the cost of surgical procedure, surgical suite and recovery room. The OP group had only a single charge for the surgical procedure, reflecting comparative cost savings for this group. Even with overnight stay (>10 hours), cost savings were 2.5 times greater for the OS group than the HA group. Comorbid disease had minimal impact on admission status between the groups; in the HA group, notable history included MI, angina and depression for 3 of the 17 cases. Hypertension, arthritis and smoking were common in all groups. HA and OP groups were of similar age; those that required extended (overnight) stay post-operatively were older. Conclusions demonstrated outpatient surgery is a reasonable choice regardless of comorbid disease; age may necessitate extended stay. Simply changing mode of admission from hospital to outpatient offers substantial financial savings to both patient and health care delivery system. Project results were presented to an interdisciplinary conference of medical and nursing staff and served as an impetus for initiating a critical pathway for women undergoing outpatient breast cancer surgery. Expanding nursing roles are recommended to manage pre-op assessment, provide caregiver education, and maintain self-care regimens; this teamwork is expected to nurture positive outcomes in the outpatient setting.

*Supported [in part] by Department of Defense Grant No. DAMD 17-94-J-4449; standard disclaimers apply.

- **Poster presentation at the Department of Defense Era of Hope Breast Cancer Conference, Washington, DC, November 14, 1997.**

EVALUATION OF NURSING CARE FOR WOMEN WITH NEWLY DIAGNOSED BREAST CANCER

**Laurie Ritz RN, MS; Laurel Decher PhD; Brad Farrell BS;
Karen Swenson RN, MS; Lynne Schroeder RN, MS;
Mary Sladek RN, MS; & Paul W. Sperduto MD, MPP**

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Developing cost-effective care while maintaining quality outcomes in breast cancer diagnosis and treatment is essential for the present health care environment. The intricacy of the health care system including the number of caregivers involved, complexities of diagnostic tests and procedures, and technical factors involved in treatment can overwhelm patients receiving care for newly diagnosed breast cancer. The use of an advanced practice nurse (APN) may ease the patient's way through the health care system. The purpose of this randomized clinical trial is to study the impact of an APN on the cost of care and quality of life for women newly diagnosed with breast cancer. Upon enrolling in the study, participants are randomized to either the control or intervention group for a period of two years. The control group receive standard medical care while the intervention group receive standard medical care plus advanced nursing care. Advanced nursing care is based on an expanded Brooten's Cost-Quality Model and the standards of advanced practice in oncology nursing. The nurse coordinates care, monitors symptoms, provides education, delivers direct patient care individualized to patient needs, and applies research-based findings to clinical practice to improve quality while decreasing costs.

The quality of life of each participant is measured by the Functional Assessment of Cancer Therapy (FACT-B), Profile of Mood States (POMS), and Mishel Uncertainty in Illness Scale (MUIS) instruments. These measurements are collected at seven different times during the two year period of enrollment.

Keywords: Nursing, Quality of Life, Cost Model, Outcomes, Cost-Effectiveness

This work was supported by the U.S. Army Medical Research and Materiel Command under DAMD17-94-J-4449.

The costs of care for each participant are measured by multiple instruments. Each participant documents hospitalizations, emergency room visits, and physician visits, as well as telephone calls to health care providers, support services used, and patient/family

days lost from work. Provider billing systems are queried for costs incurred by the participants in a two year interval beginning at the date of positive biopsy. A cost model was developed to assist with the analysis of the participants' costs as shown below (Figure 1). The categories of in-system and out-of-system refer to Methodist Hospital and Park Nicollet Clinics (in-system) and other providers of health care (out-of-system). Cancer-related and non-cancer-related categories were based on the International Classification of Diseases, 9th revision (ICD-9) codes.

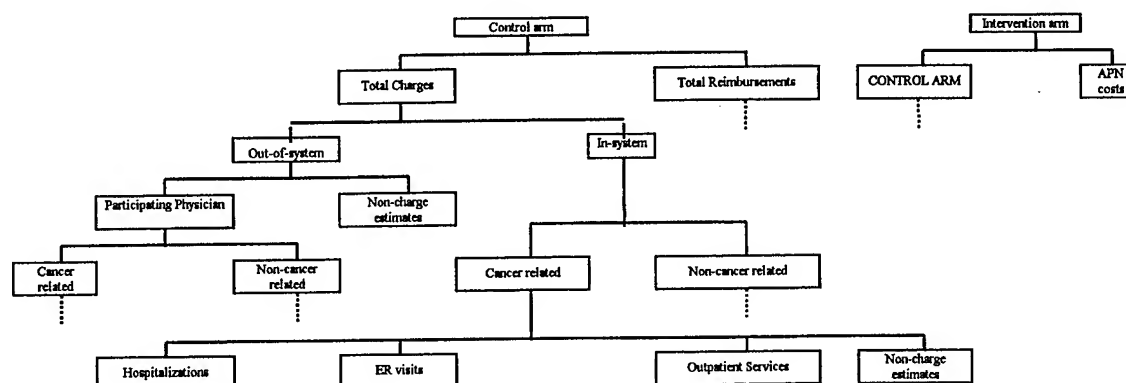


Figure 1. Cost Model

Of 554 patients diagnosed with breast cancer during the enrollment period, 81 refused to participate, 81 were not referred to the study by their physician, and 188 were ineligible for the study. Reasons for the high percentage of ineligibility (34%) are primarily due to the patient having a previous diagnosis of cancer or receiving care outside of the system. Refusal to participate (14%) has been lower than anticipated. The remaining 204 patients decided to participate, with attrition (9%) occurring at half the projected rate.

Enrollment was completed in May, 1997, reaching the planned sample size of 100 in each group. With an alpha of 0.05 and statistical power of 0.80, the smallest detectable differences between the intervention and the control arms are 6 points on the FACT-B scale, 8 points on the Mishel scale, and 3 points on the POMS scale.

Thirteen participants have finished their two year period of enrollment. The quality of life measurements are being completed at a high rate. The cost model provides the needed framework to organize and collect patient costs of care including their charges, reimbursement, and nonbillable costs. The APN intervention has been successfully implemented. Analysis must await the completion of the follow-up period, but anecdotal evidence suggests the intervention has had a positive impact.

**Podium presentation at the Seventh Annual Nursing Research Conference, Mayo Clinic,
Rochester, MN, February 16, 1998.**

COST COMPARISON OF BREAST CANCER SURGERY: OUTPATIENT SURGERY VERSUS HOSPITAL ADMISSION

Mary Sladek, RN, MS, OCN
Lynne Schroeder, RN, MS(c), OCN
Laurie Ritz, RN, MSN, OCN

In a Midwest healthcare facility, 96% of breast cancer patients were hospitalized for 1-3 days following lumpectomy or modified radical mastectomy in 1995. Recent cost containment mandated change, reducing length of stay. A retrospective pilot study* was initiated comparing age, comorbid disease and cost for outpatient versus hospital surgical admission. A convenience sample of 32 consecutive cases included 17 hospital admissions (HA) with overnight stay (≤ 24 hrs.) and 15 outpatient (OP) admissions discharged in ≤ 10 hours for subtotal mastectomy with axillary dissection. Charge data and chart audits determined cost and outcome; age and comorbidity were analyzed. Three OP cases required overnight stays (OS) due to complications. Average age for groups were: HA = 62 years, OP = 58 years, OS = 70 years. Average hospital charges were \$4,909 (HA), \$1,234 (OP), and \$1,872 (OS). Cost of surgical procedure, suite and recovery room inflated HA expense to 4 times greater than OP. Addition of overnight stay with OP (OS) cost less than HA, reflecting comparative cost savings for outpatient admission. Comorbid disease had minimal impact in 3 of 17 HA cases. History of hypertension, arthritis and smoking were consistent in all groups. HA and OP were similar in age; OS was older. Results demonstrate outpatient surgery is reasonable regardless of comorbid disease, although age influences length of stay. Changing mode of admission from hospital to outpatient offers substantial financial savings to patient and healthcare delivery system. Advanced practice nurses manage pre-op assessment, provide caregiver education, and maintain self-care regimens.

*Supported [in part] by Department of Defense Grant No. DAMD 17-94-J-4449; standard disclaimers apply.

- Podium presentation at the 23rd Annual Congress of the Oncology Nursing Society, San Francisco, CA, May 7-10, 1998

SATISFACTION WITH THE ONE DAY BREAST CANCER SURGERY HOME CARE NURSE PROGRAM.

Mary Sladek, RN, MS, OCN, Lynne Schroeder, RN, MS(c), OCN, and Laurie Ritz, RN,
MSN, OCN, HealthSystem Minnesota, Minneapolis, MN 55416.

Despite minimal changes in surgical practice, there is a trend towards shorter hospital stays for women who are undergoing breast cancer surgery. Today, women anticipate a same day or one day length of stay (LOS) for segmental or modified radical mastectomy. Nursing is challenged with meeting patient/family expectations in a shorter time and patient satisfaction may decrease with early discharge. Potential results include: fewer educational opportunities, less psychosocial support, added caregiver burden, and undetected complications. Concerns about negative outcomes prompted the Breast Cancer Patient Protection Act mandating 24-48 hr. hospital stay for axillary node dissection and mastectomy. However, this law extending hospital stay does not guarantee quality patient care; problems with postoperative care exist in inpatient settings as well as in outpatient settings. In the hospital, mastectomy patients are not classified as high acuity; less nursing time is allotted to them. At Methodist Hospital, HealthSystem Minnesota, an alternative to extended stay with enhanced education and psychosocial support was initiated to meet potential needs. Home care nurses visit patients 24-48 hrs. preoperatively and 24 hrs. postoperatively. Visits include assessment of patient/caregivers' functional status, surgical education, and psychosocial support. Potential benefits include: one to one education/emotional support with minimal distraction, familiar surroundings, less anxiety, an anesthesia-free environment, and detection of complications. A 12-item satisfaction survey using a Likert scale was conducted retrospectively following one day surgery (ODS) to evaluate the home care nurse program (HCNP). Of eleven patients surveyed, 73% had segmental mastectomy with axillary dissection (n=8), 9% excisional biopsy (n=1), 9% axillary dissection alone (n=1), and 9% had simple mastectomy (n=1). Questions were asked about ODS, education and emotional support, and overall satisfaction with the HCNP. Six patients (55%) recalled feeling uncomfortable prior to having ODS; following surgery, 64% were satisfied with the ODS experience (n=7). Ten patients (91%) felt the education and emotional support was helpful. Overall satisfaction with the ODS HCNP was positive for 91% of the patients (n=10). Additionally, six ODS nurses were surveyed with four items on patient preparedness and satisfaction. Responses included: patients were more prepared for surgery than other ODS patients, education was more expedient, and the HCNP is beneficial and should be implemented in both outpatient and inpatient settings. In conclusion, patients and staff were satisfied with the HCNP. Results suggest home care nurse visits can be an effective alternative to extended hospital stay providing the necessary care needed for successful early discharge for this population.*

*Supported [in part] by Department of Defense Grant No. DAMD17-94-J-4449.

- Podium presentation at the 23rd Annual Congress of the Oncology Nursing Society, San Francisco, CA, May 7-10, 1998.

PHYSICIAN ATTITUDES TOWARDS THE ADVANCED PRACTICE NURSE'S ROLE IN CARE OF WOMEN WITH BREAST CANCER. Laurie J. Ritz, RN, MSN, OCN*; J. Brad Farrell, BS; and Karen K. Swenson, RN, MS, OCN*, HealthSystem Minnesota, Minneapolis, MN 55426.

An ongoing challenge in healthcare is decreasing costs while improving the quality of patient care. Quality and cost outcomes of care provided by the advanced practice nurse (APN) specially prepared to care for women with breast cancer are currently being studied in a randomized clinical trial.* Over 200 women have enrolled in this study in which the control group receives traditional care while the intervention group receives traditional care plus the interventions of an APN. Data analyses of these outcomes are awaiting participant completion of the trial. While these outcomes are critical to successful change of health care delivery and implementation of the APN role, so too is physician support and attitudes toward the APN role. To assist in identifying physicians' opinions, they were surveyed about the APN role (as based on the *Standards of Advanced Practice in Oncology Nursing*, 1990) for women diagnosed with breast cancer. Nineteen physicians (53%) caring for women diagnosed with breast cancer and having the opportunity to work with the APNs, completed a ten-item Likert type questionnaire developed to evaluate the effectiveness of the APN role. All practice in a heavily saturated managed care environment. Physician specialties included medical oncology (9), surgery (7), radiation oncology (1), diagnostic radiology (1), unspecified (1). Fourteen (74%) agreed/strongly agreed that the APN improved the quality of care for women diagnosed with breast cancer. Twelve (63%) agreed/strongly agreed that the APN improved patient outcomes (i.e. patients and families are less anxious, more knowledgeable). Thirteen (68%) agreed/strongly agreed that some of the physicians' work was and/or could be done by an APN to relieve their workload. Thirteen (68%) also agreed/strongly agreed that they would support implementation of the APN role. Physician uncertainty was also evident in the surveys. Eleven (58%) were uncertain if the APN role prompted more immediate interventions for patient problems than what occurs in standard practice. Thirteen (68%) did not know if costs of care for women diagnosed with breast cancer decreased as a result of the APN role. Ten (53%) were uncertain if costs of care could be further decreased and quality of care improved by implementation of a permanent APN role. The role of the APN in the care of women with breast cancer was supported by the physicians but uncertainty about the role was identified. This uncertainty must be diminished through additional role clarification in patient care, through education, and through research. With physician support and role efficacy demonstrated in quality and cost outcomes, the APN role should become established in care of women diagnosed with breast cancer.

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- Poster presentation at the 5th National Conference on Cancer Nursing Research, sponsored by the American Cancer Society, Newport Beach, CA, February 11-13, 1999.
- Podium presentation at the 24th Annual Congress of the Oncology Nursing Society, Atlanta, GA, April 28-May 1, 1999.
- Podium presentation at the University of Minnesota School of Nursing Spring Research Day, "Achieving Excellence in Nursing through Research," Minneapolis, MN, May 4, 1999.

**DISCHARGE READINESS AND SATISFACTION AMONG BREAST CANCER
PATIENTS RECEIVING
PRESURGICAL EDUCATION FROM ADVANCED PRACTICE NURSES.**

**Robin M. Lally, BA, BSN, RN, MS (c), Mary Sladek, RN, MS, OCN,
Karen K. Swenson, RN, MS, OCN,
HealthSystem Minnesota, Minneapolis, MN 55416.**

Assuring optimal surgical experiences and positive outcomes for women undergoing breast cancer surgery are primary goals of oncology nurses. The Oncology Nursing Society's 1998 position on "Short-Stay Surgery for Breast Cancer" states that patients and healthcare providers must play a primary role in length-of-stay decisions, and that presurgical patient/caregiver assessment, education, and preparation for self-care at home are essential for short-stay breast cancer surgery. Therefore, the purpose of this study was to evaluate discharge readiness and satisfaction with presurgical preparation among breast cancer patients receiving individualized presurgical education from Advanced Practice Nurses (APNs). This quasi-experimental study was conducted as part of a larger study measuring the effectiveness of APN intervention with newly diagnosed breast cancer patients.* A convenience sample of consecutive patients (N= 50) was recruited from a surgical clinic. The sample consisted of women newly diagnosed with any stage of breast cancer, without prior diagnosis of breast cancer, who were 18 years of age or older, and undergoing any type of breast cancer surgery. Within one week prior to surgery, patients and available family/caregivers met with one of two APNs for a 30-60 minute individualized educational session. Anatomy, pathology, post-operative symptom management, care of incisions and drains, home self-care environment, and psychosocial issues were discussed to the extent required by the surgical procedure and patient needs. Breast display models and drains were used for demonstration. Written care guides and home self-care supplies were provided. An investigator-developed questionnaire assessed discharge readiness and satisfaction. The questionnaire was piloted with patients for readability and clarity, consensual validity determined through expert review, and revisions made. The questionnaire, which consists of 15 questions answered on 5-point Likert scales ranging from "strongly disagree" (1) to "strongly agree" (5), was mailed to patients 3 weeks after surgery. Final data analysis will be performed using descriptive statistics and correlation of discharge readiness and satisfaction with demographic variables. Preliminary analysis indicates that all patients either agree (29%) or strongly agree (71%), that the presurgical preparation was helpful. Of patients undergoing lumpectomy/axillary lymph node dissection, 83% indicated readiness for discharge on post-op day 1. The results of this study will assist other nurses in designing presurgical educational sessions which satisfy the needs of women with breast cancer and promote discharge readiness.

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EFFECTS OF ADVANCED NURSING CARE ON COSTS AND QUALITY OF LIFE OF WOMEN NEWLY DIAGNOSED WITH BREAST CANCER

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The purpose of this randomized clinical trial is to evaluate the impact of an advanced practice nurse on the cost of care and quality of life for women newly diagnosed with breast cancer. The control group receives standard medical care while the experimental group receives standard medical care plus advanced practice nursing care. Interventions of the advanced practice nurses (APN) include coordination of care, education, direct care, and support. The two year study has been completed by 135/210 (64%) women. Univariate analyses indicate uncertainty decreased on the Mishel Uncertainty in Illness Scale (MUIS) from baseline significantly more in the intervention group than the control group at 1 month ($p=.001$), 3 months ($p=.026$), and 6 months ($p=.011$) after diagnosis. At 12 months the two groups showed similar decreases in uncertainty ($p=.589$). The intervention group showed greater reduction of the MUIS-sub-scales of complexity, inconsistency, and unpredictability ($p=.002$, $.004$, $.008$ respectively). Changes in mood states and well-being did not differ significantly in the four follow-up periods which have received preliminary analysis. Cost of care data has been collected for 118/210 (56%) participants and is defined in terms of charges and reimbursements. The costs of care include all patient encounters with health care providers. These encounters are categorized into inpatient hospitalizations, outpatient hospital visits, emergency room visits, clinic visits, urgent care visits, and home care visits. After data is collected for the entire sample, analysis of the cost data will determine if any significant differences exist in overall costs as well as in the defined categories after taking into account the cost of an APN in the experimental group. Translation of study results into clinical practice is occurring concurrent with interpretation of results.

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Poster presentation at the 24th Annual Congress of the Oncology Nursing Society, Atlanta, GA, April 28- May 1, 1999.

**PATIENT PREPAREDNESS: RESPONDING TO THE NEEDS OF WOMEN
UNDERGOING BREAST CANCER SURGERY**

Mary Sladek, RN, MS, OCN, Robin Lally, RN, BA, BSN, MS(c), & Laurie Ritz, RN, MSN, AOCN
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As hospital stays become shorter following breast cancer surgery, nursing support and education must be provided in alternative ways. Early discharge can potentiate elevated anxiety among patients and families charged with responsibility of their personal care at home. Driven by our health system's commitment to achieve best possible patient outcomes and satisfaction with health care, information was sought from random breast cancer patients who previously underwent surgery about how our health care system could improve care for future patients. The overall concern expressed by women was that they did not feel prepared for postoperative care, e.g., how to care for drainage tubes and wound dressings, pain management, and arm exercises. Considering their suggestions, several tools were developed to assist women with their surgical experience. First, because of difficulty retaining information during a stressful time, a booklet, entitled, "Care Guide for Breast Cancer Surgery," serves as a resource to guide the preoperative educational session. It provides information on what women can anticipate during the perioperative period, caring for drainage tubes, symptom management, and a discussion of emotional issues. A variance list was created detailing each surgeon's potential postoperative instructions, e.g., how often to strip the drainage tube. This allows incorporation of each patient's own surgeon's instructions into the care guide preoperatively. Second, a care package containing items to assist women with their postoperative cares was assembled and is distributed to patients free of charge. Items include: 1) a tank top undergarment which temporarily replaces a bra and provides breast support for lumpectomy or mastectomy patients. This inexpensive undergarment may contain possible leakage from the drains/incisions, and the drain tube can be secured to it with a safety pin salvaging the patient's clothing; 2) an absorbent underpad, gauze pads, and paper tape used for leaking drainage tubes or incisions; and 3) lotion to aid in stripping the drainage tube. Costs of the supplies were covered by obtaining grant monies from the hospital's foundation, soliciting companies to donate products, and requesting store discounts. In evaluating the tools, 15 of 15 patients (100%) agree or strongly agree that the education reviewed in the booklet was helpful, and 14 of 15 patients (93%) agree or strongly agree that the supplies were useful. These tools will continue to be evaluated by future patients. In conclusion, early discharge of breast cancer patients is feasible if patients are given necessary means to prepare them for the experience. As nurses, we must continue to be accountable for achieving positive patient care outcomes amid many changes in health care. Not only should we listen to patient concerns, but we must provide tools necessary to empower women during this crisis time.*

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A Critical Pathway for Patients Undergoing One-Day Breast Cancer Surgery

As the trend of surgical procedures shifting from inpatient to outpatient settings continues, outpatient-focused standardized care processes will become more of a necessity. A multidisciplinary critical pathway (CP) for breast cancer surgery can assist care providers in meeting patients' educational and psychosocial needs. The CP document discussed in this article takes into account the expedient nature of outpatient surgery and spans the continuum of care from the surgical clinic to the postoperative homecare visit. Integrating homecare nursing improves the quality and consistency of care.

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Karen K. Swenson,
Laurie J. Ritz, and
Lynne M. Schroeder

The average length of a hospital stay for women undergoing breast cancer surgery has decreased significantly in the past five years despite minimal changes in surgical practice. At the authors' institution, the average hospital stay in 1993 was greater than two days following mastectomy and greater than one day following a partial mastectomy. By 1997, the average length of stay had decreased to approximately one day following mastectomy and less than 24 hours following partial mastectomy. A similar reduction in length of stay has been observed across the United States (Burke, Zabka, McCarver, & Singletary, 1997; Goodman & Mendez, 1993; Hoehn, 1996).

Those who control payment for services are driving many of the changes occurring in health care (Gadacz, Adkins, & O'Leary, 1997). Because of the expense associated with hospitalizations, increasing numbers of surgical procedures previously performed in inpatient settings routinely are performed in one-day surgery (ODS) centers. In addition, third-party payors strengthen patients' incentive to use

outpatient surgery instead of inpatient surgery by requiring higher deductibles for inpatient surgery (Pauly & Erder, 1993).

Using retrospective data from one institution, the authors evaluated the difference in charges between ODS and hospital admissions for 32 patients (17 hospital admissions and 15 outpatients) having a partial mastectomy and axillary dissection for breast cancer (Sladek & Schroeder, 1997). Three outpatient cases required overnight stays due to complications such as nausea, pain, and sedation. Charges for hospital admissions following surgery were four times greater than those of ODS, mainly because of expenses associated with the recovery room and inpatient room. This retrospective study demonstrated that simply changing from inpatient to outpatient surgery offered a substantial decrease in cost.

With the large number of women hospitalized annually for surgical treatment of breast cancer, efforts have focused on containing hospital costs and reducing length of stay. In addition to cost effectiveness, other positive out-

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Preoperatively, the admission process and physical preparation of the patient consume the bulk of nursing time, leaving minimal time for education, reinforcement, and emotional support.

comes of outpatient surgery exist. Patients are able to resume usual activities sooner, have a greater sense of control, and have a more positive attitude toward outcome and rehabilitation (Goodman & Mendez, 1993; Kambouris, 1996; Weltz, Greengrass, & Lyerly, 1995). When compared to patients having inpatient surgery, surgical outpatients require less pain medication and have similar complication (e.g., infection, seroma formation, arm swelling) rates (Bundred et al., 1998; Burke et al., 1997; Goodman & Mendez; McManus, Topp, & Hopkins, 1994).

In general, surgery can constitute a crisis time for patients and their families. In addition to coping with a potentially life-threatening illness, ODS patients must deal with fear of the procedure and anesthesia, an unfamiliar environment, and worry about child care and transportation arrangements, all of which increase anxiety (Lancaster, 1997). High levels of anxiety and stress experienced before surgery can negatively affect the amount of information patients retain (Bean, 1990; Beddows, 1997). ODS also causes healthcare providers to worry about not having enough time for education and psychosocial support, the potential for lack of continuity of care, and potential complications (Burke et al., 1997; Hoehn, 1996; Lancaster, 1997). Preoperatively, the admission process and physical preparation of the patient consume the bulk of nursing time, leaving minimal time for education, reinforcement, and emotional support.

Public concern about length of hospital stays has prompted some states to enact a law requiring all health plans to offer 24- or 48-hour hospital stays for patients having axillary dissection or mastectomy, respectively. On the federal level, the Breast Cancer Patient Protection Act of 1999 (H.R. 116) has been reintroduced in this year's legislature. However, a longer hospital stay does not guarantee quality care. Problems with postoperative care exist in both inpatient and outpatient settings as nurses are challenged to care for

more patients with less staff. Women undergoing mastectomies seldom are classified as high acuity inpatients, so less nursing time is allotted for them. As traditional inpatient surgery shifts to the outpatient setting, healthcare providers are responsible for offering alternative approaches for enhancing patient care. Consequently, to facilitate quality care for patients undergoing breast cancer surgery, the authors' institution developed a critical pathway (CP) that incorporates homecare nursing.

Critical Pathway Development

A CP is a treatment regimen with time-dependent functions used to standardize the care process throughout a treatment course. The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) recommends that healthcare facilities develop and use CPs to improve outcomes (Weiland, 1997). The purpose is to assist patients in a specified diagnostic-related group (DRG) to achieve positive outcomes (e.g., greater satisfaction with care and reductions in length of stay, complications, and cost) (Colucciello & Mangles, 1997; Weiland). For surgical patients, demonstration of self-care, adequate pain management, and return to preoperative activity need to be achieved prior to discharge. Patients undergoing an axillary lymph node dissection with either mastectomy or partial mastectomy have similar care needs and potential complications, making it possible to use a CP to decrease variances in process outcomes. The majority of CPs currently in use are structured for inpatient settings. As the trend for surgical procedures increasingly shifts from inpatient to outpatient settings, focused standardized care processes will be a necessity.

At the authors' institution, a multidisciplinary team of surgeons, nurses, and other healthcare professionals developed a CP for breast cancer surgery (see pp. 101-102). Communication and documentation of care delivery were



Critical Pathway for Surgical Breast Cancer Patients

Front Side

Patient Last Name, First and Middle	
DOB	MR#
Date	Int
Name	

PHASE SOURCE		PRE-ADMISSION		Date		ADDRESSOGRAPH	
				A			
1	CONSULTS	DISCHARGE OUTCOMES	PRE-ADMISSION	Date		Date of Surgery:	Surgeon:
2	TESTS		<input type="checkbox"/> Surgeon <input type="checkbox"/> Radiation Oncologist <input type="checkbox"/> Oncologist <input type="checkbox"/> Plastic Surgeon <input type="checkbox"/> Breast Cancer Nurse Coordinator <input type="checkbox"/> CBC <input type="checkbox"/> CXR pm <input type="checkbox"/> Oncology Profile pm <input type="checkbox"/> EKG pm <input type="checkbox"/> Patient education <input type="checkbox"/> Shared Decision-making Film <input type="checkbox"/> Single Session Support Group for Newly Diagnosed Cancer Patients			NURSE PROGRESS NOTES	
3	NURSING ACTIVITIES/TREATMENTS	Patient will recover free of complications - Lungs clear per baseline - VSS; temperature below 100°F - Will attempt to void before discharge; will call the doctor if unable to void within 8-10 hours after surgery - Incision dry/intact	<input type="checkbox"/> One Day Surgery / Day of Surgery Arrival pamphlet <input type="checkbox"/> Care Guide for Breast Cancer Surgery <input type="checkbox"/> Breast Cancer booklet				
4	MEDICATIONS	Patient will verbalize effective pain/nausea management Patient will verbalize understanding of the medications use, dose, route and side effects	<input type="checkbox"/> Patient education <input type="checkbox"/> Pain assessment scale <input type="checkbox"/> Side effects of medications				
5	DIET	Patient will tolerate 500cc of fluids; no vomiting noted	<input type="checkbox"/> Patient education <input type="checkbox"/> NPO after midnight before day of surgery <input type="checkbox"/> ADAT following surgery				
6	ACTIVITY	Maintain patient safety; ambulate 25 feet without dizziness or pre-hospital ADL's	<input type="checkbox"/> Patient education <input type="checkbox"/> Post-op activities				
7	PATIENT/FAMILY TEACHING/DISCHARGE PLANNING	Patient will verbalize understanding of discharge instructions Patient will verbalize understanding of JP management of clot/bleeding	<input type="checkbox"/> Patient education <input type="checkbox"/> Care Guide for Breast Cancer Surgery <input type="checkbox"/> Assessment of home support and transportation				

Critical Pathway for Surgical Breast Cancer Patients

Reverse Side

Date	Int	Name

PHASE SOURCE	ADDRESSOGRAPH			
	PREOP SURGERY	B	PACU	POSTOP
1 CONSULTS	_____ Anesthesia			_____ Home Care referral, pm _____ Home Care referral, pm
2 TESTS			_____ Hgb, pm	
3 NURSING ACTIVITIES/ TREATMENTS	_____ Reinforce education _____ Complete Nurse Progress Form • Baseline VS • IV started • Void on call _____ Consent Form signed		_____ C & DB q 2 hours _____ VS per routine _____ I&O _____ Drain care (Call Dr. if > 100 cc/hr of drainage from JP) _____ Wound management (call Dr. if drainage saturates dressing)	_____ Reinforce education _____ Discontinue IV 2 hours after tolerating fluids _____ Void pm; patient to notify doctor/nurse if bladder pain/distention is noted
4 MEDICATIONS	• Allergy assessment _____ Administer IV antibiotic, pm within 1 hr of surgery		_____ IV/IM pain med, pm _____ IV/IM antiemetic, pm	_____ Switch IV/IM meds to oral. Discharge with prescription for: • Antibiotic, pm • Pain medication
5 DIET	_____ NPO		_____ NPO	_____ When sedation decreased, begin clear liquids; ADAT
6 ACTIVITY	_____ Up ad lib		_____ Turn if necessary	_____ Dangle; up in chair; ambulate with assistance or resume normal activity _____ Arm limitations per surgeon, pm
7 PATIENT/ FAMILY TEACHING/ DISCHARGE PLANNING	_____ Cough & deep breathe _____ Pain management _____ Transportation arranged (Patient to be discharged 5-8 hrs. after admitted to One Day Surgery or shortly after they receive discharge instructions accompanied by a responsible adult).		_____ Explain DC instructions: incision & up care, medications, activity, self-care at home, pain management, Iu visit with surgeon _____ Transportation arrives	_____ Ambulate or resume normal activity

key components in the successful implementation of the CP. The breast cancer nurse coordinators facilitated implementation of the CP, developed an educational guide for homecare nurses and patients, and served as consultants for resolution of problems encountered during the process. Patient-education materials were standardized across settings, and in-services were given to care providers in each setting. The CP integrates standards of nursing care (Oncology Nursing Society & American Nurses Association, 1996) and the specific practice requirements for the majority of the surgeons. This CP is unique because it takes into account the expedient nature of outpatient surgery and, therefore, is initiated in the surgery clinic when the patient is scheduled for surgery. The CP spans the continuum of care and includes the clinic, outpatient surgery department, hospital, and home setting. Another unique characteristic of the CP is its inclusion of homecare nurse visits both preoperatively and postoperatively.

With shorter hospital stays, the traditional role of inpatient nursing involving education and support is transferred to the outpatient setting (Hoehn, 1996). Thorough preoperative education is necessary for quality patient care. The majority of patients want information about medical aspects of their illness, preparation for and recovery from surgery and anesthesia, and who to contact with questions (Breemhaar, van den Borne, & Mullen, 1996). Adequate preoperative education reduces patients' anxieties, prepares them to assume responsibility for their postoperative care, and advises them when and where to seek additional help (Martin, 1996; Page & Beresford, 1988). The breast cancer surgery CP encompasses patient teaching, emotional support, and discharge planning. The CP is initiated 24–48 hours preoperatively by the homecare nurse, continues during the hospital stay, and concludes approximately 24 hours after discharge with an additional home visit. Because the CP crosses the continuum of care, it requires collabora-

tive efforts from inpatient and outpatient healthcare providers.

Homecare nurses with prior oncology experience were given a detailed orientation to better prepare them for caring for patients with breast cancer. This orientation included observation of a breast cancer surgery, in-services on the management of incisions, drains, and complications, and a discussion of psychosocial issues encountered by these patients. A comprehensive education booklet was developed to guide the homecare nurses through the educational process and serve as a patient resource. In addition, a list of each surgeon's postsurgical preferences (e.g., bathing, arm exercises) was compiled to serve as a resource when educating individual patients.

The objectives of homecare nurse visits include assessment, education, and psychosocial support (see Table 1). Preoperatively, the homecare nurse evaluates the safety of the home environment and assesses comorbidities that may put the patient at increased risk for developing complications. This prehospital evaluation helps to identify problems that may preclude early discharge and offers an opportunity for early intervention to prevent problems (Patterson, Whitley, & Porter, 1997). After surgery, the homecare nurse assesses the patient for complications and intervenes when necessary. The homecare nurse also provides extensive patient and family education,

The critical pathway spans the continuum of care and includes the clinic, outpatient surgery department, hospital, and home setting.

Table 1. Interventions of Homecare Nurses

Preoperative	Postoperative
Assess living situation and care giver support.	Assess for surgical complications.
Assess psychosocial needs; initiate referrals as needed.	Assist with psychosocial needs.
Identify comorbidities, and assess additional care needed because of comorbid conditions.	Assess comorbidity conditions.
Educate about surgery, potential complications, and recovery process.	Reinforce education.
Initiate discharge planning.	Reinforce discharge teaching.

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Initiate discharge planning.	Reinforce discharge teaching.

which includes verbal and hands-on instruction about the surgery; information about procedures for managing incisions, dressings, and drain care; a description of potential complications; guidelines for maximizing pain control; an overview of arm exercises; and transportation recommendations.

The homecare visit also creates a unique opportunity for addressing the psychosocial needs of patients and their families. Psychosocial care is vitally important for patients undergoing breast cancer surgery because not only do they undergo a surgical procedure but they also have a potentially life-threatening disease. Within a home environment, a thorough psychosocial assessment can be obtained without the distraction of other patients or activities that usually are encountered in a busy outpatient surgery center.

Implementation

Surgical clinic staff initiate the individualized CP by notifying the homecare agency when a patient is scheduled for one-day breast cancer surgery. A referral sheet, which includes the date, type of surgery, and pertinent patient information, is faxed to the homecare nurse. The homecare nurse then contacts the patient to schedule a home visit 24–48 hours before surgery. During this visit, the homecare nurse educates the patient, assesses the home, conducts a psychosocial assessment, offers support, and completes the preadmission portion of the CP form. The CP form then is forwarded to the ODS center, where the surgical nurse reinforces educational information given by the homecare nurse, provides care for the patient perioperatively, and completes the perioperative portion of the form. After surgery, the CP and discharge instructions are faxed back to the homecare agency. The homecare nurse visits the patient within 24 hours after surgery to assess pain management, drains/incisions, and emotional status and then completes the CP form by writing a summary progress note. The CP form then is sent to the medical

record department for placement in the patient's chart. If a patient does not meet the discharge criteria because of complications, an overnight hospital stay is arranged. Additional space is provided on the CP form for continuing documentation, if needed, in the inpatient setting.

The first version of the CP included only women who were candidates for ODS. Contraindications to ODS include extensive comorbid disease, psychiatric disorders, need for invasive intraoperative monitoring, and inadequate homecare resources (Burke et al., 1997). Nurses at the institution have since expanded the CP to include all women who are undergoing mastectomies or partial mastectomies. They also have found that most insurance companies will not reimburse homecare visits related to preoperative assessment and education. Through a homecare grant from the institution's foundation, nurses were able to provide no-cost visits for those patients not covered by insurance.

Program Evaluation

Using a 12-item mailed survey, the CP process integrating pre- and postoperative homecare nurse visits was evaluated by 11 women who underwent the following procedures: segmental mastectomy with axillary dissection (8 women), excisional biopsy (1 woman), axillary dissection alone (1 woman), and simple mastectomy (1 woman). The 11 women were surveyed about how they felt about ODS, the educational and emotional support they received, and their overall satisfaction with the homecare nurses. Eight of the 11 initially described feeling neutral to very uncomfortable when ODS was ordered. However, following surgery, nine reported satisfaction with ODS. Education and emotional support were rated highly. Regarding overall satisfaction with the ODS program, seven women were very satisfied, three were satisfied, and one was neutral. Anecdotal remarks included "I felt too anxious to be taught

Within a home environment, a thorough psychosocial assessment can be obtained without the distraction of other patients or activities that usually are encountered in a busy outpatient surgery center.

immediately before surgery and appreciated being taught by the homecare nurse"; "The homecare nurse had very practical ideas"; "The homecare nurse answered a lot of my questions"; and "The nurse made me feel more comfortable."

Six ODS nurses were surveyed about patient preparedness and satisfaction with the CP incorporating homecare nurse visits. All six felt that patients were more prepared for surgery than other ODS patients with breast cancer, five felt that education and care were more expedient, and all six felt that the homecare nurse visits were beneficial. Further study is needed to evaluate quality of care, overall patient satisfaction, physician and nurse satisfaction, and costs.

Summary

Implementation of a CP for breast cancer surgery has resulted in standardization of care at the authors' institution. Although staff members are in the beginning stages of implementing this CP, they have secured the support and cooperation of the surgeons and nurses across care settings. Upon the implementation of a computer system in the outpatient clinics and hospital, the process of documentation and communication using the CP will be improved. This also will eliminate some of the paperwork and decrease the amount of time currently spent to implement the CP across settings.

The process of outpatient surgery is fast-paced; therefore, the CP can be instituted in clinic settings as a beginning framework for achieving positive patient-care outcomes. The CP facilitates optimal use of all available resources across the continuum of care and throughout the patient's surgical course. To allay public concern about potential problems with early discharge for breast cancer surgery, the incorporation of homecare nurses with a CP may be the most reasonable approach. A CP that incorporates all aspects of the patient's care from breast cancer diagnosis through recovery

from surgery may help to improve quality of care while maintaining cost-effectiveness. Provision of pre- and postoperative care by homecare nurses, in a collaborative effort with other surgical staff, is an effective alternative to a hospital admission.

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The process of outpatient surgery is fast-paced; therefore, the critical pathway can be instituted in clinic settings as a beginning framework for achieving positive patient-care outcomes.

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For more information on this topic, visit the following Web sites:

American Cancer Society:
Breast Cancer Network
<http://www.cancer.org/bcn/bcn.html>

National Alliance of Breast Cancer Organizations
<http://www.nabco.org/>

Department of Defense Breast Cancer Guide
<http://www.bcdg.org/>

These Web sites are provided for information only. Hosts are responsible for their own content and availability. Links can be found using ONS Online at www.ons.org.

- **Poster presentation at the "Seeking Excellence in Breast Cancer Care," Conference sponsored by The Institute for Johns Hopkins Nursing and the Johns Hopkins Breast Center, September 30 to October 2, 1999, Baltimore, MD.**

**Innovative Services of Advanced Practice Nurses
Meet the Challenges of Breast Cancer Care.**

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Multiple treatment modalities, life-altering decisions, shortened hospitalizations, and the psychosocial issues of a cancer diagnosis all contribute to the complex nature of breast cancer care. The six components of the advanced practice nurse (APN) role (coordinator, educator, administrator, consultant, caregiver, and researcher) are ideally suited to help patients meet these challenges. At HealthSystem Minnesota, an integrated healthcare system, two APNs provide individualized care for approximately 300 breast cancer patients annually. These Breast Cancer Nurses (BCNs)* intervene throughout the continuum of care from diagnosis through post-treatment follow-up. Innovative services provided to enhance patients' experiences include: advocacy, interdisciplinary consultation, individualized pre-operative and chemotherapy education, support service referrals, evening/weekend availability, and home care visits. Additionally, BCNs work to standardize and promote continuity of breast cancer care, conduct inservices, act as community resources, develop educational materials, and conduct, utilize, and disseminate research findings. To promote best practices in patient care and outcomes, a continuous quality improvement measure was initiated. Surveys seek input of patients at 1 and 6 months following surgery, specifically targeting the coordinator, educator, and direct caregiver roles of the BCNs. Preliminary results indicate that 100% of patients are satisfied with the care provided by BCNs. Patients also "agree" to "very strongly agree" that BCNs provide beneficial education (94%), direct care (100%), and care coordination (80%). Final analysis will provide additional stratification within these categories. Implementation of the BCN role promotes excellence in breast cancer care by enhancing patient satisfaction and preparing women to meet the challenges of this complex diagnosis.

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RESEARCH TO PRACTICE: OPERATIONALIZING THE BREAST CANCER NURSE COORDINATOR ROLE

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The Breast Cancer Nurse Coordinator (BCNC) role was implemented as part of a research study* evaluating the cost effectiveness of advanced practice nurses (APNs) and their impact on patients' quality of life. BCNCs provided education, coordination, and direct care which improved overall mood of a subset of patients, decreased uncertainty, and strengthened patient satisfaction. On a one-month post-op survey, patients indicated satisfaction with the amount of time BCNCs spent with them. Therefore, to advance this role into practice, BCNC time allocation was evaluated. This sub-study's purpose was to determine time utilized during patient contacts (hospital, clinic, phone, home care, administrative) and staffing needs; characteristics of patients utilizing BCNC time; and appropriate duration of BCNC/patient relationships. Contact time, length, and interventions were recorded for a convenience sample (n= 47) during a 6-month period. Results indicate 1293 contacts with 358 intervention hours were made (avg. 7.6 hrs/patient). Nearly half of BCNC time (3.5 hrs/patient) was spent within one month of diagnosis. Patients <40 years old, never married, or having regional disease required more BCNC time. Most patients (69%) reported that working with BCNCs for six months was a satisfactory duration, however, many comments suggested that longer follow-up is desired. Time calculations for new and recurrent breast cancers demonstrated that two full-time BCNCs are necessary to care for the 300+ patients treated annually at our integrated healthcare system. Measurement of time, quality of life, and satisfaction provide important data for making administrative decisions and operationalizing this APN role into practice.

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VOICES OF WOMEN WITH BREAST CANCER

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The purpose of the Department of Defense study funded in 1994, was to evaluate the quality of life (QOL) and cost outcomes of an advanced practice nurse's intervention with women newly diagnosed with breast cancer. The purpose of this qualitative study which complements the randomized trial, is to further describe QOL outcomes. Of 210 women, 143 (68%) who participated in the randomized trial, commented regarding QOL experiences. Comments were included in diary narratives, phone call notes, letters, and open-ended questionnaire responses. Using Weber's content analysis methodology (1990), three categories were derived which reflected the shared meanings of the text. "Recovering physical self" describes the journey through treatment in terms of physical and functional well being. Women described dealing with day-to-day issues surrounding decision making; wound management; and symptoms such as pain, nausea, and fatigue. "Reconstituting emotional integrity" describes the experiences of attempting to regain emotional well being. Women described dealing with altered body image, feelings of isolation, feelings of constant anxiety, depression, and living with intimacy concerns. "Moving beyond the illness experience" illustrates the women's growth toward sustained health as a result of breast cancer. They described personal growth; movement beyond the negative consequences of the illness; a fighting spirit; and a renewed interest in nature, faith, and civic responsibilities. Multiple recommendations and implications for advanced nursing practice and multidisciplinary care for women with breast cancer are derived from the text. Preliminary analysis indicates that many implications surround issues where APNs made a significant difference in meeting women's voiced needs. Needs include preparatory guidance, education, and consistent emotional support through the breast cancer experience. Additionally, the categories and descriptors add depth to the original study and suggest expansion of Brooten's cost-quality model (1986) adapted for the quantitative study. Expanding the model to reflect the women's experiences further guides practitioners in treatment of women with breast cancer and has implications for use in future research.

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- **Podium presentation at the Oncology Nursing Society 25th Annual Congress, San Antonio, TX, May 11-14, 2000,**

EFFECTS OF ADVANCED NURSING CARE ON QUALITY OF LIFE AND COST OUTCOMES OF WOMEN DIAGNOSED WITH BREAST CANCER

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Using Brooten's cost-quality model, this study determined if advanced practice nurses (APNs) improve quality of life (QOL) and decrease costs of care of women newly diagnosed with breast cancer. The study randomized 210 women meeting eligibility criteria. The control group received standard medical care. The intervention group received standard care plus APN interventions described in the Oncology Nursing Society's APN standards. QOL was measured by tests with established reliability and validity including Functional Assessment of Cancer Therapy (FACT-B), Mishel Uncertainty in Illness Scale (MUIS), and Profile of Mood States (POMS) at seven intervals over two years. Costs of care (charges and reimbursement) were collected through billing records during the study period. Analysis of QOL data used multiple regression methods for repeated measures; for cost data, multiple regression on logarithmic transform of charges and reimbursements was used. Uncertainty decreased significantly more from baseline in the intervention vs. control group at 1, 3, and 6 months ($p=.001, .026, .011$ respectively) after diagnosis with the strongest effect on subscales of complexity, inconsistency, and unpredictability. POMS and FACT-B scores did not differ except unmarried women in the intervention group showed significantly greater improvement at 1 and 3 months. No significant differences were found between intervention and control costs. Conclusions are APN interventions improved some QOL indicators and did not significantly affect costs. APNs should intervene with research-proven strategies. Shorter interventions, critical paths, reimbursement, and physician time are being studied to improve APN role efficacy and outcomes with women newly diagnosed with breast cancer.

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Effects of Advanced Nursing Care on Quality of Life and Cost Outcomes of Women Diagnosed With Breast Cancer

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Purpose/Objectives: To evaluate quality of life (QOL) and cost outcomes of advanced practice nurses' (APNs') interventions with women diagnosed with breast cancer.

Design: Randomized clinical trial.

Setting: Integrated healthcare system in a midwestern suburban community.

Sample: 210 women with newly diagnosed breast cancer, with an age range of 30–85 years.

Methods: The control group ($n = 104$) received standard medical care. The intervention group ($n = 106$) received standard care plus APN interventions based on Brotoen's cost-quality model and the Oncology Nursing Society's standards of advanced practice in oncology nursing. QOL was measured using the Functional Assessment of Cancer Therapy, Mishel Uncertainty in Illness Scale, and Profile of Mood States at seven intervals over two years. Information about costs (charges and reimbursement) was collected through billing systems.

Main Research Variables: Uncertainty, mood states, well-being, charges, and reimbursement.

Findings: Uncertainty decreased significantly more from baseline in the intervention versus control group at one, three, and six months after diagnosis ($p = 0.001$, 0.026 , and 0.011 , respectively), with the strongest effect on subscales of complexity, inconsistency, and unpredictability. Unmarried women and women with no family history of breast cancer benefited from nurse interventions in mood states and well-being. No significant cost differences were found.

Conclusions: APN interventions improved some QOL indicators but did not raise or lower costs.

Implication for Nursing Practice: The first six months after breast cancer diagnosis is a critical time during which APN interventions can improve QOL outcomes. More research is necessary to define cost-effective interventions.

Key Points . . .

- Nurse-sensitive patient outcomes are becoming increasingly more important to identify
- Subjective (e.g., quality of life) and objective (e.g., length of stay, cost of care) factors can be considered when determining the effects of nursing care.
- Well-designed clinical studies are necessary to determine nursing care delivery changes that improve quality outcomes and are cost-effective
- Studies of cost and quality factors need to be conducted across all settings

today's healthcare environment. Some factors that result in compromised outcomes include the complexity of medical information, shortened hospital stays, and communication with numerous healthcare providers (Boman, Andersson, & Bjorvell, 1997; Lerman et al., 1993; Wang, Cosby, Harris, & Liu, 1999). High levels of distress immediately following diagnosis are reported with associated insomnia,

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Breast cancer accounts for almost one-third of all cancers in women in the United States. In 2000, an estimated 182,800 new cases will be diagnosed and 40,800 women will die of breast cancer (Greenlee, Murray, Bolden, & Wingo, 2000). Finding cost-effective methods to manage care for women with breast cancer while achieving quality outcomes is a major challenge in

mood disturbance, fatigue, loss of concentration, and avoidance coping (Cimprich, 1999; McCaul et al., 1999). While patients are undergoing treatment, quality of life (QOL) often is compromised by symptoms such as fatigue, pain, hot flashes, sleep disturbances, and nausea and vomiting (Irvine, Vincent, Graydon, & Bubela, 1998; Macquart-Moulin et al., 1997; Ozyilkan, Baltali, Tekuzman, &

Firar, 1998; Wyatt & Friedman, 1998). Although QOL improves after treatment is completed, patients may continue to experience symptoms such as fatigue, pain, lymphedema, insomnia, and sexual difficulties (Gunz, Rowland, Meyerowitz, & Desmond, 1998; Velanovich & Szymanski, 1999). Other factors, such as living alone, younger age at diagnosis, receiving adjuvant treatment, and having a

Table 1. Advanced Practice Nurse Interventions

Phase of Care	Intervention	Focus
Introduction (preoperative)	Assessment	Physical assessment General needs assessment
	Education	Availability of advanced practice nurse (APN) and role Consultation expectations Discussion on decision making
	Care coordination	Follow-up plan of care Arrange multidisciplinary consults (oncology, radiation oncology, plastics) Presence at consultations
Postoperative	Assessment	Signs of postoperative complications <ul style="list-style-type: none"> • Bleeding, infection • Pain and nausea management • Swelling, inflammation, and redness Ability to cope with changes <ul style="list-style-type: none"> • Wound care/dressing care • Drain management • Lymphedema prevention/care
	Education	Reinforce postoperative self-care Review of pathology report
	Care coordination	Reach to Recovery/prosthesis Follow-up visits with surgeon
Inpatient	Assessment	Physical well-being (hospital/clinic/home) <ul style="list-style-type: none"> • Range of motion, seroma, necrosis • Oral intake Psychosocial well-being <ul style="list-style-type: none"> • Mood • Coping • Support <ul style="list-style-type: none"> • Understanding lab values • Energy level/fatigue
	Education	Local and systemic treatments <ul style="list-style-type: none"> • Radiation therapy • Chemotherapy • Hormonal therapy
	Symptom management	<ul style="list-style-type: none"> • Fatigue • Nausea/vomiting • Constipation/diarrhea • Mouth sores <ul style="list-style-type: none"> • Hair loss • Skin changes • Hot flashes
	Care coordination	Arrange follow-up visits postoperatively. Presence at follow-up visits
	Consultation and referral	Social services, mental health, physical therapy Community support groups
Post-treatment follow-up	Assessment	<ul style="list-style-type: none"> • Treatment recovery • Psychosocial needs/coping • Quality of life • Lymphedema prevention/care <ul style="list-style-type: none"> • Sexuality • Nutritional status • Activities of daily living
	Education	General health promotion Fatigue management Complementary therapies
	Care coordination	Follow-up visits Mammograms

Table 2. Patient Characteristics

Variable	Intervention Group (n = 106)		Control Group (n = 104)		P
Mean age (years)	55.7		55.3		0.79
Mean education (years)	14.1 (n = 103)		14.3 (n = 91)		0.61
Mean tumor size (cm)	2.0		2.1		0.57
	n	%	n	%	
Race					0.90
White	103	97	101	97	
Asian	2	2	1	1	
African American	1	1	1	1	
American Indian	0	0	1	1	
Marital status					0.76
Single, never married	11	10	15	14	
Married	74	70	70	67	
Divorced	8	8	9	9	
Widowed	13	12	10	10	
Income					0.08
Under \$31,000	24	23	26	25	
\$31,000-\$50,999	22	21	22	21	
\$51,000-\$70,999	21	20	7	7	
\$71,000-\$90,999	11	10	17	16	
\$91,000 or more	18	17	14	14	
Not provided	10	9	18	17	
Insurance					0.68
HMO	60	57	53	51	
Non-HMO	22	21	26	25	
Medicare/medical assistance	24	23	25	24	
Extent of disease (Surveillance, Epidemiology and End Results Stage)					0.11
In situ	12	11	8	8	
Localized	49	46	65	63	
Regional	43	41	29	28	
Distant	2	2	2	2	
Histology					0.04
Grade 1, well differentiated	15	14	16	15	
Grade 2, moderately differentiated	55	52	41	39	
Grade 3, poorly differentiated	29	27	45	43	
Grade 4, undifferentiated	7	7	2	2	
Family history of breast cancer					0.34
Yes	46	43	52	50	
No	60	57	52	50	
Comorbidity^a					0.09
Yes	22	21	13	13	
No	84	79	91	87	
Definitive surgical treatment					0.34
Mastectomy	49	46	55	53	
Lumpectomy	57	54	49	47	
Radiation therapy					0.17
Yes	68	64	57	55	
No	38	36	47	45	
Chemotherapy					0.41
Yes	46	43	51	49	
No	60	57	53	51	
Reconstruction					0.21
Yes	18	17	25	24	
No	88	83	79	76	
Hormone therapy					0.03
Yes	62	59	45	43	
No	44	42	59	57	
Bone marrow transplant					0 ^b
Yes	0	0	3	3	
No	106	100	101	97	

^aComorbid conditions included in the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987)

^bSignificance level could not be calculated because no observations were available in the intervention group.

more advanced stage of cancer, may put patients at risk for diminished QOL (Chie, Huang, Chen, & Chang, 1999; Hurny et al., 1996; Vinokur, Threutt, Caplan, & Zimmerman, 1989). Women have identified the need for assistance in interpreting the vast amount of information received with the diagnosis of breast cancer and in coping with the meaning in their individual life situations (Trief & Donohue-Smith, 1996; Wang et al.).

As the multiple needs of women with newly diagnosed breast cancer are recognized, so too are the costs of care interventions. Studies have focused on costs associated with screening, treatment choices, and adjuvant drug therapies (Desch et al., 1999; Hillner, 1996; Norum, Olsen, & Wist, 1997; Zaverinik, McCoy, Robinson, & Love, 1992). However, the impact of nursing on costs for women diagnosed with breast cancer also must be studied.

An advanced practice nurse (APN) could improve quality outcomes while decreasing costs. The APN is an RN prepared with a master's degree in nursing who has in-depth knowledge and skill in the care of a specific patient population. Brooten et al. (1986) developed a model of early hospital discharge with APN interventions for low birth-weight infants and found that patient care was safe and cost-effective. This model has been adapted and found similarly effective for women having cesarean births; women with high-risk pregnancies; and hospitalized elders (Brooten et al., 1994; Naylor et al., 1999; York et al., 1997). APN interventions have been tested with other patient groups, with the interventions improving some QOL indicators, increasing patient satisfaction and knowledge, and decreasing costs of care (Aiken et al., 1993; Bissenger, Alfred, Arford, & Bellig, 1997; Dowswell, Lawler, Young, Forster, & Hearn, 1997; Greineder, Luane, & Parks, 1995; Rawl, Easton, Kwiatkowski, Zemen, & Burczyk, 1998; Shiell, Kenny, & Farnworth, 1993).

Studies of APN interventions for cancer care—including patients with lung cancer, those receiving radiation therapy, and patients who are terminally ill—have found less anxiety, greater patient knowledge, and better control of symptoms with specialized care (Addington-Hall et al., 1992; McCorkle et al., 1989; Weintraub & Hagopian, 1990). Ambler et al. (1999) found that women undergoing surgery for breast lesions were better informed, understood treatment options, and felt more involved in decision making with specialized nursing care. The intervention did not, however, significantly improve anxiety, depression, or other symptoms. Other breast cancer studies have found little or no effect of interventions on mood states and QOL, even though clinical changes were noted and patients evaluated interventions positively (Edmonds, Lockwood, & Cunningham, 1999; Rustoen, Wiklund, Hanestad, & Moum, 1998). No studies were found that reported the APN effect on costs of care for women with breast cancer. This study was undertaken to evaluate the QOL and cost outcomes of APN interventions with women with newly diagnosed breast cancer.

Methods

Framework, Design, Setting, and Sample

Brooten's cost-quality model (with minor modifications) (Brooten et al., 1988) and the Oncology Nursing

Society's (ONS's) advanced standards of practice (1990, 1997) served as the conceptual framework. Brooten's model uses APN interventions to facilitate early hospital discharge. Follow-up APN care is provided during clinic, hospital, telephone, and homecare visits. Interventions include assessment, diagnosis, outcome identification, planning, coordination, symptom management, health education, consultation, and research as based on the ONS standards of advanced practice.

The institutional review board approved this randomized clinical trial, which was conducted at an integrated health-care system in a suburban community of a large midwestern metropolitan area in the United States. The sample consisted of women 21 years of age and older who were diagnosed with breast cancer between 1995 and 1997. Subjects were able to read and write English and give informed consent. Exclusion criteria were a history of cancer, comorbidities that limited functional ability, or severe psychiatric illness. Physician referral, care within the system, and consent within two weeks of diagnosis were required.

Data Collection

QOL was measured using three self-administered questionnaires: the *Mishel Uncertainty in Illness Scale (MUIS)*, the *Profile of Mood States (POMS)*, and the *Functional Assessment of Cancer Therapy (FACT-B)*. The MUIS, which assessed the inability to determine the meaning of illness-related events, had high internal reliability ($\alpha = 0.93$) and convergent validity (Mishel & Epstein, 1990). Higher MUIS scores reflected greater uncertainty. The POMS included scales of six mood states. Internal reliability was high, with indices near 0.90 or above, and validity has been documented in several studies, including studies of psychological adjustment to breast cancer (McNair, Lorr, & Droppleman, 1992; Spiegel, Bloom, & Yalom, 1981; Taylor et al., 1985; Taylor, Lichtman, & Wood, 1984). Higher POMS scores reflected greater mood disturbance. The FACT-B measured QOL on six dimensions in individuals with breast cancer. It has high internal reliability ($\alpha = 0.90$), and evidence supports its convergent, divergent, and known groups' validity (Brady et al., 1997; Cella, 1996). Higher FACT-B scores reflected greater well-being.

Cost data (charges and reimbursements) were collected from hospital and clinic billing systems for two years after the date of diagnosis for each participant. Clinic reimbursements were calculated by multiplying clinic charges by a collection factor: net revenue received from a participant's insurance divided by the gross charges assessed to this insurance. Provider fees for the anesthesiologists, emergency room physicians, and radiation oncologists were inaccessible and were not included in the analyses. Data were categorized by the type of encounter (inpatient hospitalization, outpatient/clinic visit, emergency room visit, urgent care visit, and homecare visit) and referenced to the time frames of 0–6 months, 6–12 months, 12–18 months, and 18–24 months. In addition to charges and reimbursements, length of hospitalization and number of visits to a healthcare provider were recorded.

Measures of the cost of APN services were based on time logs in which each APN recorded the number of minutes spent with each patient during hospitalizations, clinic

visits, home visits, telephone calls, and administrative work. APN cost of service per patient was equal to the average hourly salary plus benefits multiplied by the mean APN time/patient. A travel cost of \$0.315 per mile was added for homecare visits.

Procedure

The hospital's pathology department identified patients for potential participation. After eligibility criteria were verified and informed consents obtained, the women were assigned randomly to one of two groups. Women in the control group received standard medical care, and women in the intervention group received standard medical care plus APN care.

For the intervention group, the initial APN contact was within two weeks of diagnosis and included written and verbal information about breast cancer, what to expect in consultations with physicians, decision-making support, answering questions, and presence for support. Subsequent contacts were made with the patients at their scheduled clinic visits or by telephone, home visits, or patient-initiated visits to reinforce information, provide continuity of care, and offer ongoing support (see Table 1). Contacts were based on need as determined by the patient, family, and APNs. One of two APNs was on-call from 8 am–8 pm Monday through Friday and from 8 am–noon on weekends.

Participants received sets of questionnaires with pre-stamped return envelopes at enrollment into the study and by mail 1, 3, 6, 12, 18, and 24 months after enrollment. All questionnaires were to be returned within one week of receiving them. Women who did not return questionnaires received reminder letters mailed after two weeks, telephone calls after four weeks, and additional letters and sets of questionnaires as required.

Statistical Analysis

Univariate analyses of demographic and QOL data used the *t*-test for continuous variables and either the chi-square test or Fisher's exact test for categorical variables. Analyses of QOL data used multiple regression methods for repeated measures (GENMOD procedure, SAS Institute, Inc., 1997) and included QOL baseline scores as a covariate. Therefore, analyses of scores at 1, 3, 6, and 12 months controlled for baseline and essentially assessed differences from baseline. Other factors were included as covariates if they affected the QOL scale being analyzed, particularly if intervention and control groups tended to differ on that factor. Because charges, reimbursements, and number of healthcare visits normally were not distributed, the nonparametric Wilcoxon-Mann-Whitney test (Stokes, Davis, & Koch, 1995) was used for univariate analyses of these variables. Multivariate regression analyses were conducted on the natural logarithmic transformation of these variables, which showed more normal distributions. All tests were two-tailed and were considered statistically significant at $p < 0.05$.

Results

Patient Characteristics

Of 558 women with newly diagnosed breast cancer who were screened during the study enrollment period, 85

(15%) were not referred to the study by their physicians. Of the 473 referred patients, 177 (37%) did not meet eligibility criteria. Of the 296 eligible patients, 211 (71%) agreed to participate and were randomized to either the intervention group ($n = 106$) or the control group ($n = 105$). One patient in the control group was restaged to a noncancerous condition after enrolling, decreasing the control group to 104 patients. Study participants and nonparticipants did not differ significantly in race, marital status, histology, tumor size, number of positive nodes, method of detecting the breast cancer, or presence of a family history of breast cancer. Participants were younger ($p < 0.0001$) than nonparticipants, however, and were more likely to have invasive disease ($p = 0.003$).

The randomization process produced intervention and control groups that were similar demographically and in characteristics of disease at diagnosis and treatment (see Table 2) with two exceptions. Women in the intervention group were significantly more likely to have a lower histology ($p = 0.04$) and to receive adjuvant hormone therapy ($p = 0.03$) than women in the control group.

Analyses of cost data included 141 participants (74 in intervention and 67 in control) for whom all cost data were available and 11 participants (4 in intervention and 7 in control) for whom all cost data were available except for a few procedures or visits at nonsystem facilities. These missing values were imputed, using the mean cost of the procedure or visit for similar participants. The remaining 58 participants (28 in intervention and 30 in control) were missing substantial amounts of data on costs either because they were referred for only oncology care or because they moved, changed insurance, or transferred care to non-system facilities. They were excluded from cost analyses.

Quality of Life

QOL analyses focused on baseline through 12 months for three reasons: (a) the number responding beyond 12 months was low, with the proportion of women who returned QOL questionnaires ranging from 95% at baseline to 76% at 24 months in the intervention group and from 76% at baseline to 52% at 24 months in the control group, (b) the APN intervention itself was reduced beyond 12 months because of decreased patient needs, and (c) comparisons between intervention and control groups on QOL scales and subscales showed no significant differences beyond 12 months ($p > 0.05$). Overall, scores on the MUIS decreased somewhat at 18 and 24 months, whereas scores on the POMS and FACT-B scales showed little change beyond 12 months.

Intervention and control groups did not differ significantly on any of the QOL scales at baseline. Figures 1, 2, and 3 show adjusted mean scores on the MUIS, POMS, and FACT-B scales, respectively, at 1, 3, 6, and 12 months.

Uncertainty

The intervention group showed significantly less uncertainty than the control group ($p = 0.043$) after adjustment for baseline, extent of disease, and hormone therapy. Uncertainty was significantly lower in the intervention group than the control group at 1 month ($p = 0.001$), 3 months ($p = 0.026$), and 6 months ($p = 0.011$) but not at 12 months

($p = 0.589$). In addition, uncertainty increased significantly at one month following baseline in the control group ($p = 0.010$) but not in the intervention group. The beneficial effect of the APN intervention was greater for unmarried women than for married women (p value for the interaction of group assignment and marital status = 0.017).

Analyses were conducted on each of the four subscales of the MUIS to elucidate further effects of the APN interventions. The intervention group had significantly lower scores than the control group on complexity, inconsistency, and unpredictability subscales ($p = 0.005$, 0.005, and 0.038, respectively).

Mood

Intervention and control groups did not differ significantly in POMS scores ($p = 0.953$) in analyses adjusted for baseline, age, and family history of breast cancer. Among unmarried women, however, mood disturbance decreased from baseline significantly more in the intervention group than the control group at one month ($p = 0.011$) and three months ($p = 0.043$). Analyses also showed that among women with no family history of breast cancer, mood disturbance decreased from baseline significantly more in the intervention group than the control group at one month ($p = 0.002$), three months ($p = 0.010$), and six months ($p = 0.004$).

None of the six subscales of the POMS showed significant differences between intervention and control groups when both married and unmarried women were included in the analysis. When analysis was restricted to unmarried women, however, the intervention group showed significantly lower scores than the control group on the following subscales: Tension-Anxiety ($p = 0.027$), Depression-Dejection, ($p = 0.004$), and Anger-Hostility ($p = 0.028$).

Well-Being

Intervention and control groups did not differ significantly on FACT-B scores ($p = 0.895$) or on any of the subscales after adjustment for baseline, age, and extent of disease. Among unmarried women, those in the intervention group tended to have greater well-being than those in

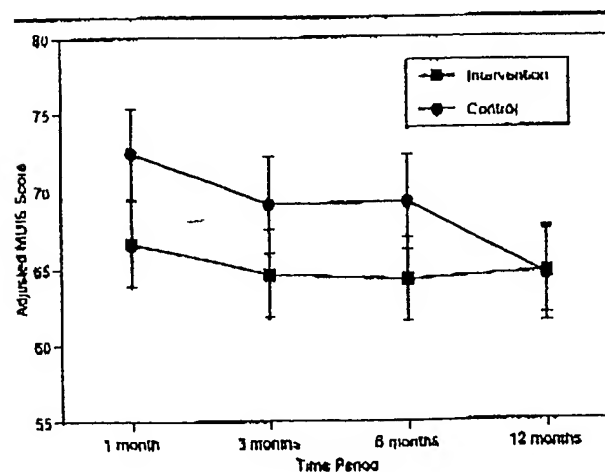


Figure 1. Mean Adjusted Mishel Uncertainty in Illness Scale (MUIS) Scores With 95% Confidence Limits (Higher Scores Indicate Greater Uncertainty)

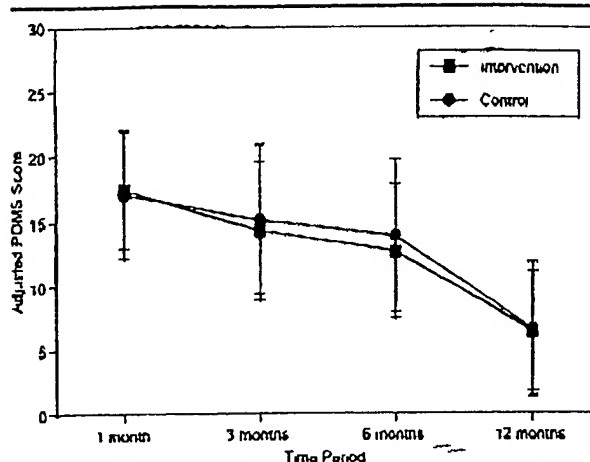


Figure 2. Mean Adjusted Profile of Mood States (POMS) Scores With 95% Confidence Limits (Higher Scores Indicate Greater Mood Disturbance)

the control group. This advantage was significant at one month following baseline ($p = 0.036$).

Overall Costs

Table 3 shows overall charges and reimbursements during the two-year study period. No significant differences existed between intervention and control groups in either overall charges or reimbursements or those categorized by source (inpatient, outpatient/clinic, home care, emergency room/urgent care). Intervention and control groups did not differ significantly on length of stay for definitive surgery, length of stay for admissions following definitive surgery, or number of healthcare visits either overall or according to type (see Table 4). Figures 4–6 portray how median charges, reimbursements, and number of visits were dominated by the first six-month period, declined sharply after six months, and remained relatively steady thereafter. Intervention and control groups did not differ significantly in charges, reimbursements, or number of visits in any of the six-month periods (all p values > 0.05). Subgroups

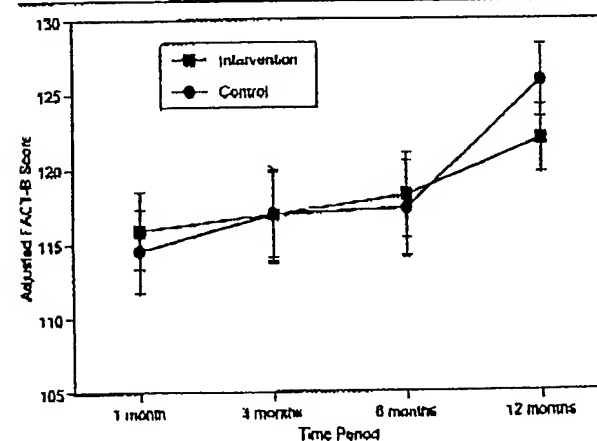


Figure 3. Mean Adjusted Functional Assessment of Cancer Therapy (FACT-B) Scores With 95% Confidence Limits (Higher Scores Indicate Greater Well-Being)

Table 3. Distribution of Charges, Reimbursements, and Frequencies for Intervention (n = 78) and Control (n = 74) Groups for the Two-Year Study Period

Cost Measures	Intervention	Control	Difference	p
Overall charges				
\bar{x}	\$34,100	\$32,399	1,701	0.128
Median	\$29,506	\$26,079		
Range	\$12,020-\$109,591	\$9,149-\$141,734		
SD	\$19,245	\$25,481		
Overall reimbursement				
\bar{x}	\$23,946	\$23,476	470	0.305
Median	\$18,713	\$18,460		
Range	\$6,361-\$70,467	\$4,071-\$114,998		
SD	\$14,510	\$20,149		
Categories of charges (\bar{x})				
Inpatient	\$12,336	\$11,979	357	0.336
Outpatient/clinic	\$21,587	\$20,116	1,471	0.197
Home care	\$52	\$149	-97	0.233
Emergency room/urgent care	\$125	\$156	-31	0.120
Categories of reimbursement (\bar{x})				
Inpatient	\$8,319	\$8,130	189	0.425
Outpatient/clinic	\$15,498	\$15,130	368	0.430
Home care	\$39	\$118	-79	0.246
Emergency room/urgent care	\$90	\$99	-9	0.142

stratified by age, marital status, extent of disease, participation in cancer trials, and survival status showed no significant differences in costs between the intervention and control groups

Costs of Advanced Practice Nurse Services

Table 5 shows APN time and cost per patient, including categorization by type of APN service. Overall, APN mean time per patient was 1,377 minutes, for a mean cost of \$629 per patient. Seventy-five percent of APN time (and cost) occurred during either clinic or telephone visits. APN time per patient was greatest (746 minutes) during the first six months, dropped substantially in the second and third six-month periods (301 and 170 minutes, respectively), and was least (159 minutes per patient) during the last six months

Discussion

APN interventions effectively improve QOL and decrease costs in many patient populations. In some groups

of patients with cancer, APN interventions have improved QOL, but no cost studies have been conducted. This study was designed to determine whether APN interventions improve QOL and reduce costs

In this study, interventions performed by APNs significantly improved several aspects of QOL for women with newly diagnosed breast cancer. During each of three measurement periods, uncertainty decreased significantly more in the intervention group than in the control group. Uncertainty actually increased in the control group at one month from baseline. The increased level of uncertainty at this vulnerable time after breast cancer diagnosis reflects patients' need for assistance to sort through and process information

The APN interventions significantly improved women's perceptions of the complexity, inconsistency, and unpredictability of information about their illness and outcome. With the continuity of care and information provided by the APNs, the intervention patients found their treatment and system of care easier to understand, were less likely to receive conflicting or changing information, and consid-

Table 4. Mean Length of Stay for Definitive Surgery and Later Admissions; Mean Number of Outpatient/Clinic, Homecare, and Emergency Room/Urgent-Care Visits for Intervention (n = 78) and Control (n = 74) Groups for the Two-Year Study Period

Cost Measures	Intervention	Control	Difference	p
Mean length of stay for definitive surgery (hours)	36.67	38.91	-2.24	0.303
Mean length of stay for all inpatient admissions following definitive surgery (days)	1.94	1.12	0.82	0.364
Mean number of visits overall	69.03	67	2.03	0.500
Inpatient visits	1.15	0.86	0.29	0.205
Outpatient/clinic visits	66.77	64.04	2.73	0.409
Homecare visits	0.36	1.14	-0.78	0.245
Emergency room/urgent-care visits	0.74	0.96	-0.22	0.097

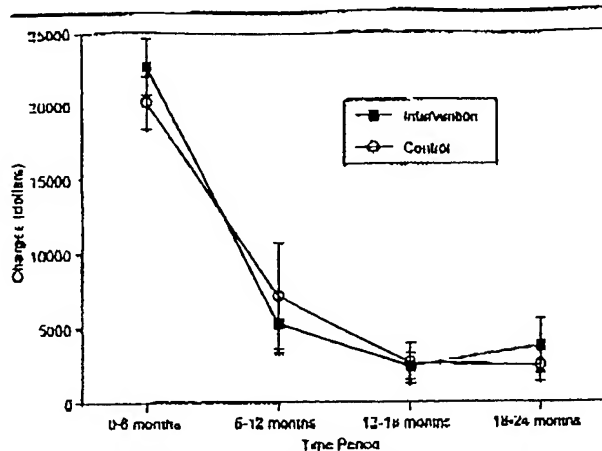


Figure 4. Mean Charges With 95% Confidence Limits

ered their illness and treatment more predictable than control patients. The coordination of care may have improved the adjustment to the diagnosis and treatment, as was suggested in Christman's (1990) study of uncertainty during radiotherapy.

Some subgroups of patients benefited more than others from the APN interventions. These encounters improved mood and well-being and decreased uncertainty for unmarried women. Unmarried women in the intervention group also showed greater improvement in the subscales of anxiety, depression, and anger than unmarried women in the control group. Social support is recognized as a key factor in the acute adjustment to the diagnosis and treatment of cancer (Richardson et al., 1997; Wang et al., 1999). Perhaps unmarried women did not have as much support as married women and benefited more from APN support and other interventions. In mood states, women without a family history of breast cancer benefited more from the APN interventions than women with a family history, indicating that the APN interventions were more important for women without prior family experience with breast cancer.

As in other studies (Ambler et al., 1999; Irvine et al., 1998), QOL indicators were most compromised in the first

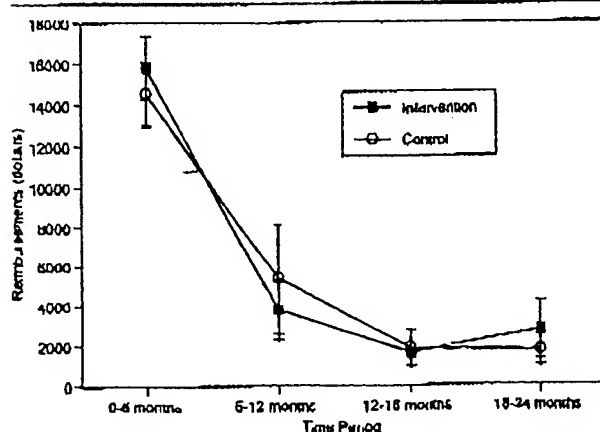


Figure 5. Mean Reimbursements With 95% Confidence Limits

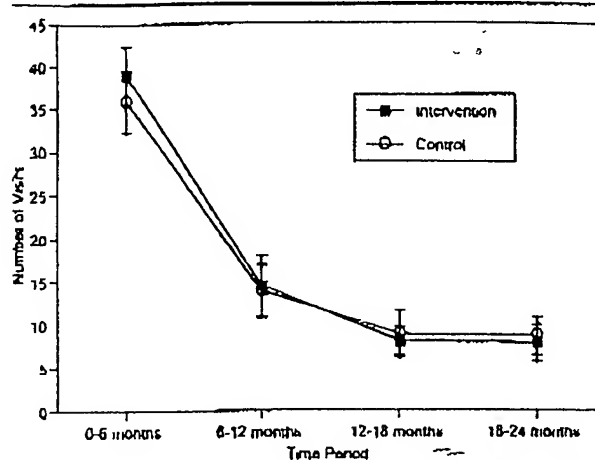


Figure 6. Mean Number of Healthcare Visits With 95% Confidence Limits

six months after diagnosis. The decreased need for the interventions for longer time intervals may account for the absence of group differences beyond this initial time period. Interventions that are shorter, more structured, and more focused to the first six months after diagnosis may be appropriate.

Unfortunately, the results showed that costs of care were not decreased by the interventions. Several possible reasons exist for this lack of a significant difference between the two groups. The highest source of charges came from clinic/outpatient visits (see Table 3), and many of these could not be altered by APN interventions. For example, more than half of the intervention (64%) and control groups (55%) were treated with 33-37 radiation treatments, and more than 40% of both groups received chemotherapy. The hypothetical savings provided by the APN interventions may not have been large enough to offset the high treatment-related costs during these clinic/outpatient visits.

Second, an average of 41 patient-APN phone interactions also complemented the care of women in the intervention group. These phone interactions may have decreased uncertainty and physician work load as was recognized by many of the physicians and has been demonstrated in telephone triage studies (Gallagher, Huddart,

Table 5. Distribution of Advanced Practice Nurse Time and Cost Per Patient According to Type of Service

Advanced Practice Nurse (APN) Service	Mean APN Time/Patient (Minutes)	Mean Cost of Service/Patient
Overall	1,377	\$629
Clinic visits	683	\$307
Hospital visits	83	\$37
Telephone visits	368	\$166
Homecare visits ^a	55	\$34
Administrative	188	\$ 85

^aThe mileage cost of 0.315/mile x 29.1 miles (average distance traveled) has been added to the cost of the homecare visit.

& Henderson, 1998; Poole, Schmitt, Carruth, Peterson-Smith, & Slusarski, 1993). However, the number of outpatient visits was not decreased in the intervention group. This finding supports the need to study whether APN visits could replace some of the physician visits in the outpatient setting, thus reducing costs.

Readmissions and emergency and urgent-care visits were minimal for the intervention and control groups and did not substantially contribute to cost of care. The average hospital length of stay was similar between groups for the initial breast surgery, with 33% of the women staying less than 24 hours. APN interventions did not decrease the length of stay three possible reasons: (a) physician impact on discharge time, (b) length of stay already minimized for this group of patients, and (c) pending legislation through the Patients' Bill of Rights Plus Act of 1999 (S.1344, Sec. 715/H.R. 116) regulating length of stay for patients requiring breast cancer surgery. The ONS position statement (1998) for breast cancer surgery further supports length of stay based on individual physical and psychological ability to manage at home. Other studies showed significant cost savings with the APN interventions because of the reduction in hospital length of stay, readmissions, emergency room or urgent-care visits (Brooten et al., 1986; Greineder et al., 1995; Naylor et al., 1999; Shiell et al., 1993; York et al., 1997).

Limitations of this randomized trial also must be considered. The study sample primarily included Caucasian, middle-income women with a high level of education. Standardization of care and a competitive managed-care environment provide the impetus not only to decrease costs but to continually implement changes that improve quality of care. Process improvements were implemented during the study period that may have improved overall care and made statistically significant results more difficult to ascertain. Analyses of the actions of a single provider group like APNs may be difficult to isolate when other providers in the course of treatment also influence patient outcomes. In addition, even though QOL is considered to be a nurse-sensitive patient outcome, it may elude standard

psychometric evaluation (Brooten & Naylor, 1995; Carroll & Fay, 1997; Edmonds et al., 1999; Rustoen et al., 1998). Missing data on both QOL and cost measures may have contributed to a lack of power in the analyses.

Implications for Practice

The improved QOL outcomes indicate a need to establish APN interventions in care settings for women with newly diagnosed breast cancer. Patient needs during the first six months after diagnosis provide rationale to focus interventions on this time period and to develop less costly interventions, as was done in a follow-up study to this randomized trial. Future studies are necessary to determine whether quality and cost outcomes are improved and physician time is decreased by APN interventions. Reimbursement for APN interventions, integration of components of the APN role with those of other providers, and other methods of making the position cost-effective while continuing to improve QOL must be developed and studied.

Conclusions

Women with newly diagnosed breast cancer have multiple needs requiring APN interventions. Uncertainty decreased significantly during the first six months after diagnosis for women who received the APN interventions. The APN interventions significantly improved moods and well-being for unmarried women and improved well-being in women with no family history of breast cancer. Significant cost differences were not recognized in this study. Further research is critical to maximizing the QOL of women diagnosed with breast cancer while successfully controlling healthcare costs.

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Initials: _____

Date: _____

No. _____

MISHEL UNCERTAINTY IN ILLNESS SCALE

Instructions: Please read each statement. Take your time and think about what each statement says. Then place an "X" under the column that most closely measures how you are feeling TODAY. If you agree with a statement, then you would mark under either "Strongly Agree" or "Agree." If you disagree with a statement, then mark under either "Strongly Disagree" or "Disagree." If you are undecided about how you feel, then mark under "Undecided" for that statement. Please respond to every statement.

1. I don't know what is wrong with me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

2. I have a lot of questions without answers.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

3. I am unsure if my illness is getting better or worse.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

4. It is unclear how bad my pain will be.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

5. The explanations they give about my condition seem hazy to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

6. The purpose of each treatment is clear to me.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

7. When I have pain, I know what this means about my condition.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

8. I do not know when to expect things will be done to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

9. My symptoms continue to change unpredictably.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

10. I understand everything explained to me.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

11. The doctors say things to me that could have many meanings.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

12. I can predict how long my illness will last.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
-----------------------	--------------	------------------	-----------------	--------------------------

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

13. My treatment is too complex to figure out.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

14. It is difficult to know if the treatments or medications I am getting are helping.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

15. There are so many different types of staff, it's unclear who is responsible for what.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

16. Because of the unpredictability of my illness, I cannot plan for the future.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

17. The course of my illness keeps changing. I have good and bad days.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

18. It's vague to me how I will manage my care after I leave the hospital.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

19. I have been given many differing opinions about what is wrong with me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

20. It is not clear what is going to happen to me.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

21. I usually know if I am going to have a good or bad day.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
_____	_____	_____	_____	_____

22. The results of my tests are inconsistent.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

23. The effectiveness of the treatment is undetermined.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

24. It is difficult to determine how long it will be before I can care for myself.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

25. I can generally predict the course of my illness.

Strongly Agree (1)	Agree (2)	Undecided (3)	Disagree (4)	Strongly Disagree (5)
_____	_____	_____	_____	_____

26. Because of the treatment, what I can do and cannot do keeps changing.

Strongly Agree (5)	Agree (4)	Undecided (3)	Disagree (2)	Strongly Disagree (1)
_____	_____	_____	_____	_____

27. I'm certain they will not find anything else wrong with me.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

28. The treatment I am receiving has a known probability of success.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

29. They have not given me a specific diagnosis.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(5)	(4)	(3)	(2)	(1)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

30. My physical distress is predictable; I know when it is going to get better or worse.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

31. I can depend on the nurses to be there when I need them.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

32. The seriousness of my illness has been determined.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

33. The doctors and nurses use everyday language so I can understand what they are saying.

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
(1)	(2)	(3)	(4)	(5)

_____	_____	_____	_____	_____
-------	-------	-------	-------	-------

NAME _____ DATE _____

SEX: Male (M) Female (F)

Below is a list of words that describe feelings people have. Please read each one carefully. Then fill in ONE circle under the answer to the right which best describes HOW YOU HAVE BEEN FEELING DURING THE PAST WEEK INCLUDING TODAY.

The numbers refer to these phrases.

- 0 = Not at all
1 = A little
2 = Moderately
3 = Quite a bit
4 = Extremely

Col (C)

O.P. (O)

NOT AT ALL
A LITTLE
MODERATELY
QUITE A BIT
EXTREMELY

1. Friendly 0 1 2 3 4

2. Tense 0 1 2 3 4

3. Angry 0 1 2 3 4

4. Worn out 0 1 2 3 4

5. Unhappy 0 1 2 3 4

6. Clear-headed 0 1 2 3 4

7. Lively 0 1 2 3 4

8. Confused 0 1 2 3 4

9. Sorry for things done . 0 1 2 3 4

10. Shaky 0 1 2 3 4

11. Listless 0 1 2 3 4

12. Peeved 0 1 2 3 4

13. Considerate 0 1 2 3 4

14. Sad 0 1 2 3 4

15. Active 0 1 2 3 4

16. On edge 0 1 2 3 4

17. Grouchy 0 1 2 3 4

18. Blue 0 1 2 3 4

19. Energetic 0 1 2 3 4

20. Panicky 0 1 2 3 4

21. Hopeless 0 1 2 3 4

22. Relaxed 0 1 2 3 4

23. Unworthy 0 1 2 3 4

24. Spiteful 0 1 2 3 4

25. Sympathetic 0 1 2 3 4

26. Uneasy 0 1 2 3 4

27. Restless 0 1 2 3 4

28. Unable to concentrate 0 1 2 3 4

29. Fatigued 0 1 2 3 4

30. Helpful 0 1 2 3 4

31. Annoyed 0 1 2 3 4

32. Discouraged 0 1 2 3 4

33. Resentful 0 1 2 3 4

34. Nervous 0 1 2 3 4

35. Lonely 0 1 2 3 4

36. Miserable 0 1 2 3 4

37. Muddled 0 1 2 3 4

38. Cheerful 0 1 2 3 4

39. Bitter 0 1 2 3 4

40. Exhausted 0 1 2 3 4

41. Anxious 0 1 2 3 4

42. Ready to fight 0 1 2 3 4

43. Good natured 0 1 2 3 4

44. Gloomy 0 1 2 3 4

IDENTIFICATION

45. Desperate 0 1 2 3 4

46. Sluggish 0 1 2 3 4

47. Rebellious 0 1 2 3 4

48. Helpless 0 1 2 3 4

49. Weary 0 1 2 3 4

50. Bewildered 0 1 2 3 4

51. Alert 0 1 2 3 4

52. Deceived 0 1 2 3 4

53. Furious 0 1 2 3 4

54. Efficient 0 1 2 3 4

55. Trusting 0 1 2 3 4

56. Full of pep 0 1 2 3 4

57. Bad-tempered 0 1 2 3 4

58. Worthless 0 1 2 3 4

59. Forgetful 0 1 2 3 4

60. Carefree 0 1 2 3 4

61. Terrified 0 1 2 3 4

62. Guilty 0 1 2 3 4

63. Vigorous 0 1 2 3 4

64. Uncertain about things . 0 1 2 3 4

65. Bushed 0 1 2 3 4

MAKE SURE YOU HAVE
ANSWERED EVERY ITEM.



POM 021

Initials: _____

Date: _____

FACT - B (Version 3)

Below is a list of statements that other people with your illness have said are important. By circling one number per line, please indicate how true each statement has been for you during the past 7 days.

PHYSICAL WELL-BEING

not a little some- quite very
at all bit what a bit much

During the past 7 days:

- | | | | | | |
|--|---|---|---|---|---|
| 1. I have a lack of energy..... | 0 | 1 | 2 | 3 | 4 |
| 2. I have nausea..... | 0 | 1 | 2 | 3 | 4 |
| 3. Because of my physical condition, I have trouble meeting
the needs of my family..... | 0 | 1 | 2 | 3 | 4 |
| 4. I have pain..... | 0 | 1 | 2 | 3 | 4 |
| 5. I am bothered by side effects of treatment..... | 0 | 1 | 2 | 3 | 4 |
| 6. I feel sick..... | 0 | 1 | 2 | 3 | 4 |
| 7. I am forced to spend time in bed..... | 0 | 1 | 2 | 3 | 4 |

8. Looking at the above 7 questions, how much would you say your
PHYSICAL WELL-BEING affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
Not at all Very much so

SOCIAL/FAMILY WELL-BEING

not a little some- quite very
at all bit what a bit much

During the past 7 days:

- | | | | | | |
|--|---|---|---|---|---|
| 9. I feel distant from my friends..... | 0 | 1 | 2 | 3 | 4 |
| 10. I get emotional support from my family..... | 0 | 1 | 2 | 3 | 4 |
| 11. I get support from my friends and neighbors..... | 0 | 1 | 2 | 3 | 4 |
| 12. My family has accepted my illness..... | 0 | 1 | 2 | 3 | 4 |
| 13. Family communication about my illness is poor..... | 0 | 1 | 2 | 3 | 4 |
| 14. I feel close to my partner (or the person who is my main support)..... | 0 | 1 | 2 | 3 | 4 |
| 15. Have you been sexually active during the past year?
No ___ Yes ___ If yes: I am satisfied with my sex life..... | 0 | 1 | 2 | 3 | 4 |

16. Looking at the above 7 questions, how much would you say your
SOCIAL/FAMILY WELL-BEING affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
Not at all Very much so

FACT - B (Version 3)

RELATIONSHIP WITH DOCTOR

not a little some- quite very
at all bit what a bit much

During the past 7 days:

17. I have confidence in my doctor(s)..... 0 1 2 3 4
18. My doctor is available to answer my questions..... 0 1 2 3 4

19. Looking at the above 2 questions, how much would you say your

RELATIONSHIP WITH THE DOCTOR affects your quality

(circle one number)

of life?

0 1 2 3 4 5 6 7 8 9 10

Not at all

Very much so

EMOTIONAL WELL-BEING

not a little some- quite very
at all bit what a bit much

During the past 7 days:

20. I feel sad..... 0 1 2 3 4
21. I am proud of how I'm coping with my illness..... 0 1 2 3 4
22. I am losing hope in the fight against my illness..... 0 1 2 3 4
23. I feel nervous..... 0 1 2 3 4
24. I worry about dying..... 0 1 2 3 4
25. I worry that my condition will get worse..... 0 1 2 3 4

26. Looking at the above 6 questions, how much would you say your

EMOTIONAL WELL-BEING affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10

Not at all

Very much so

FUNCTIONAL WELL-BEING

not a little some- quite very
at all bit what a bit much

During the past 7 days:

27. I am able to work (include work in home)..... 0 1 2 3 4
28. My work (include work in home) is fulfilling..... 0 1 2 3 4
29. I am able to enjoy life..... 0 1 2 3 4
30. I have accepted my illness..... 0 1 2 3 4
31. I am sleeping well..... 0 1 2 3 4
32. I am enjoying the things I usually do for fun..... 0 1 2 3 4
33. I am content with the quality of my life right now..... 0 1 2 3 4

34. Looking at the above 7 questions, how much would you say your

FUNCTIONAL WELL-BEING affects your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10

Not at all

Very much so

FACT - B (Version 3)

ADDITIONAL CONCERNS

not a little some- quite very
at all bit what a bit much

During the past 7 days:

35. I have been short of breath.....	0	1	2	3	4
36. I am self-conscious about the way I dress.....	0	1	2	3	4
37. My arms are swollen or tender.....	0	1	2	3	4
38. I feel sexually attractive.....	0	1	2	3	4
39. I have been bothered by hair loss.....	0	1	2	3	4
40. I worry about the risk of cancer in other family members.....	0	1	2	3	4
41. I worry about the effect of stress on my illness.....	0	1	2	3	4
42. I am bothered by a change in weight.....	0	1	2	3	4
43. I am able to feel like a woman.....	0	1	2	3	4

44. Looking at the above 9 questions, how much would you say these

ADDITIONAL CONCERNS affect your quality of life?

(circle one number)

0 1 2 3 4 5 6 7 8 9 10
Not at all Very much so

END OF PARTICIPANT'S INVOLVEMENT IN
STUDIES 1 AND 2

SURVEYS

Initials _____

Date _____

Study Evaluation

Please read the following ten (10) statements and circle the answer closest to your impressions of this study. Write comments as you wish. Completion of this evaluation indicates your willingness to contribute to the study evaluation.

1. The questionnaires for this study were not a burden to complete.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

2. All questions on the questionnaires were important for me to answer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

3. Answering the questionnaires seven times over a period of two years was necessary to evaluate my feelings during the two year time period.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

4. The diary was not a burden to complete.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

5. The diary was an accurate way to report my health care contacts with my doctors, nurses and other health care providers.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

6. My feelings were adequately addressed by the questionnaires and diary.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

7. I feel confidentiality and my privacy is being well-maintained in this study and is not a concern in my participation and in my answers.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

8. The care I received from my doctors and nurses has been well-coordinated.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

9. I can think of ways to improve care for women with breast cancer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

10. Participation in this study makes me feel I have contributed to improving care of women who will be diagnosed and treated for breast cancer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

Summary of Patient/Family Days Lost From Work

Please answer the following question to provide an overall evaluation of this previously assessed item.

1. How much time have you and your family members lost from work because of your diagnosis of breast cancer in the past two years since enrolling in the study?

My time lost from work (check one):

- | | |
|----------------------------|---|
| (1) _____ None | (4) _____ Greater than 1 month - 6 months |
| (2) _____ Less than 1 week | (5) _____ Greater than 6 month - 1 year |
| (3) _____ 1 week - 1 month | (6) _____ Greater than 1 year |

Family members' days lost from work (check one):

- | | |
|----------------------------|---|
| (1) _____ None | (4) _____ Greater than 1 month - 6 months |
| (2) _____ Less than 1 week | (5) _____ Greater than 6 month - 1 year |
| (3) _____ 1 week - 1 month | (6) _____ Greater than 1 year |

Additional Comments

Initials _____

Date _____

Study Evaluation

Please read the following ten (10) statements and circle the answer closest to your impressions of this study. Write comments as you wish. Completion of this evaluation indicates your willingness to contribute to the study evaluation.

1. The questionnaires for this study were not a burden to complete.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

2. All questions on the questionnaires were important for me to answer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

3. Answering the questionnaires three times over a period of six months was necessary to evaluate my feelings during the six month time period.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

4. My feelings were adequately addressed by the questionnaires.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

5. I feel confidentiality and my privacy is being well-maintained in this study and is not a concern in my participation and in my answers.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

6. The care I received from my doctors and nurses has been well-coordinated.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

7. Six months is an appropriate length of time to work with the Breast Cancer Nurse Coordinator (BCNC).

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

8. I can think of ways to improve care for women with breast cancer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

9. Participation in this study makes me feel I have contributed to improving care of women who will be diagnosed and treated for breast cancer.

strongly disagree	disagree	neutral	agree	strongly agree	don't know
1	2	3	4	5	DK

Comments or suggestions: _____

Summary of Patient/Family Days Lost From Work

Please answer the following question to provide an overall evaluation.

10. How much time have you and your family members lost from work because of your diagnosis of breast cancer in the past six months since enrolling in the study?

My time lost from work (check one):

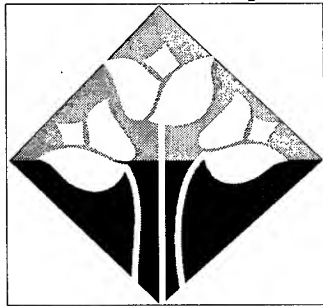
- | | |
|----------------------------|---|
| (1) _____ None | (4) _____ Greater than 1 month - 6 months |
| (2) _____ Less than 1 week | (5) _____ Greater than 6 month - 1 year |
| (3) _____ 1 week - 1 month | (6) _____ Greater than 1 year |

Family members' days lost from work (check one):

- | | |
|----------------------------|---|
| (1) _____ None | (4) _____ Greater than 1 month - 6 months |
| (2) _____ Less than 1 week | (5) _____ Greater than 6 month - 1 year |
| (3) _____ 1 week - 1 month | (6) _____ Greater than 1 year |

Additional Comments

DiARY



*A Randomized Clinical Trial
to Evaluate
Advanced Nursing Care
for Women With
Newly Diagnosed
Breast Cancer*

This is a diary especially designed for women with breast cancer. We request your cooperation in completing this diary. You will receive a new diary **every six months** for two years. Please answer questions relating to your experience over the next six months.

We are always trying to improve our quality of care. The information in this diary will help us to help you and others with breast cancer. Completion of this diary indicates your willingness and consent to assist us in collecting this information. If you have questions about this study, please call Laurie Ritz, R.N. at 993-6220. Thank you for your cooperation.

Laurie Ritz, R.N., M.S.N., O.C.N.
Paul W. Sperduto, M.D., M.P.P.

Diary Months _____ to _____

I.D.# _____

1. Name: _____

2. Date of Birth: _____ / _____ / _____
mo day yr

♦ Please complete questions 3-11 only if changes since the beginning of the study.

3. Date of Notification of Diagnosis: _____ / _____ / _____
mo day yr

4. Date of Surgery: _____ / _____ / _____
mo day yr

5. Name of Primary Doctor: _____

6. Name of Surgeon: _____

7. Name of Medical Oncologist: _____

8. Name of Radiation Oncologist: _____

9. Name of Plastic Surgeon: _____

10. Treatment:

Check all which apply:

Mastectomy Yes ☐ 1 No ☐ 2

Lumpectomy Yes ☐ 1 No ☐ 2

Radiation Yes ☐ 1 No ☐ 2

Chemotherapy Yes ☐ 1 No ☐ 2

Reconstruction Yes ☐ 1 No ☐ 2

11. Way in which your breast cancer was detected:

Date detected _____ / _____ / _____

(Check one) mo day yr

Self regular monthly exam ☐ 1
accidental finding ☐ 2

Spouse/Other ☐ 3

Mammogram ☐ 4

Doctor ☐ 5

Other _____ ☐ 6

12. Level of Activity during the week you receive this diary:
(circle only one number)

0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, i.e., light housework, office work.
2	Ambulatory and capable of all self care but unable to carry out any work activities. Up and about more than 50 percent of waking hours.
3	Capable of only limited self care. Confined to bed or chair more than 50 percent of waking hours.
4	Completely disabled. Cannot carry on any self care. Totally confined to bed or chair.

13. Hospitalizations—begin with the month you receive this diary:

[illegible]

14. Phone Calls—begin with the month you receive this diary:

[illegible]

15. Visits with Doctors and Nurses

—begin with month you receive this diary

Doctor or Nurse:	Date of visit:	Length of time of visit: (exclude wait time)		Wait Time: Time waiting to be seen by nurse, doctor.
		Start Time	End Time	
	mo / day / yr			Minutes:
Primary Doctor	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Surgeon	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Medical Oncologist	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Radiation Oncologist	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			
Plastic Surgeon	___/___/___			
	___/___/___			
	___/___/___			
Other Physician (Please write name in this space.)	___/___/___			
	___/___/___			
	___/___/___			
	___/___/___			

Doctor or Nurse:	Date of visit:	Length of Visit:		Wait Time:
		(exclude wait time)		(Time waiting to be seen by nurse, doctor.)
	mo / day / yr	Start Time	End Time	Minutes:
Nurse visits (i.e., chemotherapy)	/ /			
	/ /			
	/ /			
	/ /			
Nurse Practitioner Marcia Soules, RN, NP	/ /			
	/ /			
	/ /			
	/ /			
Nurse Coordinators Lynne Schroeder, RN or Mary Geditz, RN	/ /			
	/ /			
	/ /			
	/ /			
	/ /			
	/ /			

Was there anything which could have been
improved about your visits?

Yes ☐ 1

No ☐ 2

If yes, please identify: _____

16. Home Care Visits—begin with the month you receive this diary:

Type of Service (Doctor ₁ , nurse ₂ , nurse assistant ₃)	Date mo / day / yr	Length of Visit	
		Start Time	End Time
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
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	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		
	___/___/___		

**17. Urgent Care or Emergency Room Visits
—begin with the month you receive this diary:**

Date mo / day / yr	Name of Urgent Care or ER		Reason
	Methodist ₁	Other, specify ₂	
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			
___/___/___			

18. Support services you use—begin with the month you receive this diary.

Type of Service	Yes	No	Number of Times
Cancer Support Groups/ Services (ie. Reach to Recovery)	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Other Support Groups	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Psychologist/Social Worker	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Sex Therapist	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Chaplain	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Dietitian	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>
Other: please specify	Y	N	<div> <div>1</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> </div> <div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <div>10</div> <div>10+</div> </div>

19. Are you participating in another research study?

Yes ☐ 1 No ☐ 2

20. Are you undergoing physical therapy?

Yes ☐ 1 No ☐ 2

21. Are you using any alternative therapies such as hypnosis, vitamins, etc.?

Yes ☐ 1 No ☐ 2

If yes, please identify: _____

22. Are you employed outside your home?

Yes ☐ 1 No ☐ 2

If yes, how many hours per week are you employed?

23. Do you have children requiring daycare?

Yes ☐ 1 No ☐ 2

If yes, how many children do you have who require daycare?

How many hours of daycare time did you use per child and month prior to diagnosis?

_____ hours/month/child

_____ hours/month/child

_____ hours/month/child

_____ hours/month/child

24. How many hours of daycare time have you used per month since receiving this diary?

(Please answer this question in the chart provided on the next page).

25. How much time have you and your family members lost from work because of your diagnosis of breast cancer since receiving this diary?

(Please answer this question on the chart provided on the next page).

Please start recording information —begin with the month you receive this diary.

	Daycare Hours per Month	Your Days Lost From Work	Family Members' Days Lost From Work
January			
February			
March			
April			
May			
June			
July			
August			
September			
October			
November			
December			
TOTAL			




Notes

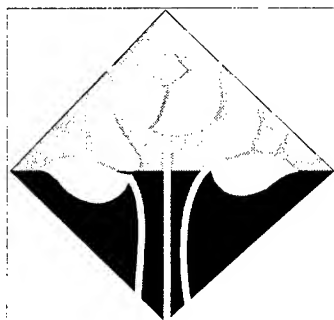
Notes





Notes

 **Methodist Hospital**
HealthSystem Minnesota



List Of Personnel Receiving Pay From The Research Effort

Dorothy Brooten
J. Brad Farrell
Christine Flugaur
Gloria Held
Robin Lally
Carol McPherson
Mary Jo Nissen
Cindy Peden-McAlpine
Laurie Ritz
Lynne Schroeder
Catherine Skrobola
Mary (Geditz) Sladek
Paul Sperduto
Karen Swenson